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Excerpt: Chapter 9

Maximizing Your Success With the Examiner

by Stuart S. Levy, Esq.

Stephen G. Kunin, Esq.



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§9.01 Introduction

The preparation, prosecution, and examination of patent applications should be a win-win-win situation for patent practitioners, their clients, and patent Examiners. Objectively, you should try to obtain a patent that will encourage investment, be easily examined, and lead to an enforceable patent that will be respected by competitors and courts of law. To this end, it is of utmost importance that patent applications be prepared efficiently and effectively so that they will undergo a smooth and rapid examination without incurring unnecessary expense. Although this is easier said than done, this chapter will provide helpful suggestions on achieving your objectives while avoiding common pitfalls faced by many practitioners.

A. *Putting Yourself in the Examiner's Shoes*

When preparing your patent application, you should consider “putting yourself in the shoes of the patent Examiner.” By doing this, it will enable

you to understand the pressure under which the Examiner is working and what motivates her. The better you understand how the Examiner thinks and operates, the greater the likelihood of your success in getting your client's patent application allowed without complication and delay.

As of the end of FY 2008, there were 6,055 Patent Examiners.¹ The journeyman Examiner² has approximately 20.5 hours³ to perform a first examination on a new application and dispose of an application⁴ that has already undergone an initial examination. This means that the average Examiner must complete roughly 75 first actions on the merits and roughly 75 disposals per year in order to achieve her production expectancy.⁵ A primary Examiner⁶ is expected to do 35 percent more work than the average Examiner,⁷ so a primary Examiner must complete approximately 100 initial actions and 100 disposals each year to be fully successful. Because Examiners receive no production credit for actions that are neither first actions on the merits nor disposals, an Examiner ideally benefits when she is able to readily examine an application without great difficulty and dispose of each application on the first office action or at least the second office action.

B. What the Examiner Wants to See

Consequently, what the typical patent Examiner wants to see when examining a new application is an application that is clear, concise, and

¹USPTO Performance and Accountability Report for FY 2008 (Nov. 7, 2008), *available at* <<http://www.uspto.gov/web/offices/com/annual/2008/index.html>>.

²Grade 12 in the GS-1224 job series.

³U.S. Dep't of Commerce Office of Inspector General, *available at* <<http://www.oig.doc.gov/oig/reports/2004/USPTO-IPE-15722-09-04.pdf>>.

⁴A disposal is typically one of allowance of the patent application, abandonment of the application, or preparation of an Examiner's answer in an application where the applicant has filed an appeal brief before the Board of Patent Appeals and Interferences.

⁵An Examiner is typically expected to work 1664 examining hours per year. The Examiner crediting system counts as a production unit one half of the sum of a first office action on the merits and a disposal.

⁶A primary Examiner is a patent Examiner with full signatory authority to sign all actions without supervisory approval. Signatory authority is granted by a Technology Center Group Director, who has been delegated the authority to bestow such authority by the Undersecretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office. Granting of signatory authority occurs after a thorough review of a sample of the Examiner's final office actions by a panel of supervisors in the Technology Center in which the Examiner works.

⁷An Examiner's production expectancy is measured in hours per production unit. The expectancy is calculated by multiplying the average hours per production unit for all technologies examined, by the complexity factor of the docket assigned to the Examiner, divided by the Examiner's position factor. A journeyman Examiner (GS-12) is assigned a position factor of 1.00. A primary Examiner (GS-14) has a position factor of 1.35.

easily understood.⁸ At least one asserted or well-established specific, substantial, and credible utility should be provided.⁹ The description should explain how the claimed invention accomplishes a practical application (i.e., how it achieves a concrete, useful, and tangible result).¹⁰ The application, to avoid scope of enablement rejections, should provide adequate support for broad, intermediate, and narrow claims presented.¹¹ Each embodiment of the invention described in the specification, in nonchemical applications, should be accompanied by its clear depiction in the drawings.¹² Most applications in the electrical arts represent a software invention in the drawings by using functional block diagrams and flowcharts.¹³ The description should use the terminology that provides support for claim limitations¹⁴ in such way that the Examiner can easily diagram the claims¹⁵ and correlate them to the supporting written description. If special definitions for claim terms are to be used, they should be clearly defined.¹⁶ Where means- or step-plus-function limitations are used in claims, clear correlation in the written description should be provided for the corresponding structure, material, and acts.¹⁷ If you intend to rely on objective indicia of nonobviousness, a foun-

⁸The Patent Act describes the “Specification” as follows:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

35 U.S.C. §112.

⁹MPEP §2107.01 (Eighth Ed., Rev. Aug. 6, 2007).

¹⁰*Id.* at §2106.

¹¹“The description is a dictionary for the claims and should provide clear support or antecedent basis for all terms used in the claims. See 37 C.F.R. 1.75, MPEP §608.01(i), §608.01(o), and §1302.01.” 608.01(g) Detailed Description of Invention.

¹²“The first sentence of 35 U.S.C 113 requires a drawing to be submitted upon filing where such drawing is necessary for the understanding of the invention.” MPEP §609 (Eighth Ed., Rev. Aug. 6, 2007).

¹³*Fonar Corp. v. General Elec. Co.*, 107 F.3d 1543, 41 USPQ2d 1801 (Fed. Cir. 1997).

¹⁴37 C.F.R. §§1.75(d) and 1.83(a).

¹⁵The Examiner draws the features described in each claim and their relationship in order to better understand the scope and content of each claim for search and examination purposes.

¹⁶“Where an explicit definition is provided by the applicant for a term, that definition will control interpretation of the term as it is used in the claim. *Toro Co. v. White Consol. Indus. Inc.*, 199 F.3d 1295, 1301, 53 USPQ2d 1065, 1069 (Fed. Cir. 1999) (meaning of words used in a claim is not construed in a ‘lexicographic vacuum, but in the context of the specification and drawings.’). . . . Any special meaning assigned to a term ‘must be sufficiently clear in the specification that any departure from common usage would be so understood by a person of experience in the field of the invention.’ *Multiform Desiccants Inc. v. Medzam Ltd.*, 133 F.3d 1473, 1477, 45 USPQ2d 1429, 1432 (Fed. Cir. 1998).” MPEP §2106 (Eighth Ed., Rev. Aug. 6, 2007).

¹⁷“If there is no disclosure of structure, material or acts for performing the recited function, the claim fails to satisfy the requirements of 35 U.S.C. 112, second paragraph. *Budde v. Harley-Davidson, Inc.*, 250 F.3d 1369, 1376, 58 USPQ2d 1801, 1806 (Fed. Cir. 2001); *Cardiac Pacemakers, Inc. v. St. Jude Med., Inc.*, 296 F.3d 1106, 1115-18, 63 USPQ2d 1725, 1731-34 (Fed. Cir. 2002) (Court interpreted the language of the ‘third monitoring means for monitoring the ECG signal for activating[.]’ to require the same means to perform both functions and the only entity referenced in the specification that could possibly perform both functions is the physician. The court held that exclud-

ation for same should be incorporated into the written description.¹⁸ Ideally, from the patent Examiner's perspective, the claims of the application should be clearly written and not too numerous.¹⁹

The basic filing fee of a patent application permits you to file up to three independent claims and 20 claims total without incurring excess claim fee charges.²⁰ For most applications, this number of claims is adequate. The more claims filed in an application, the more difficult it is for the Examiner to do her job at the highest level of quality. Even though the Examiner's production expectancy is based on averages, when an Examiner is required to read and understand an application that is more than 100 pages long and has more than the 20 claims, she finds it difficult to thoroughly examine the application while making her production quota.²¹

Ideally, an Examiner wants you to submit an information disclosure statement prior to when examination begins.²² This helps the Examiner locate the closest prior art relevant to the claimed invention by helping her determine the most probable field of search²³ and aids her in identifying the type of information she should be expected to discover as part of her search process. It is extremely beneficial if a pre-examination search is performed not only of U.S. patent and printed publications, but also of foreign patent and nonpatent literature databases.²⁴

ing the physician, no structure accomplishes the claimed dual functions. Because no structure disclosed in the embodiments of the invention actually performs the claimed dual functions, the specification lacks corresponding structure as required by 35 U.S.C. 112, sixth paragraph, and fails to comply with 35 U.S.C. 112, second paragraph.)" MPEP §2181 (Eighth Ed., Rev. Aug. 6, 2007).

¹⁸"Examiners must consider comparative data in the specification which is intended to illustrate the claimed invention in reaching a conclusion with regard to the obviousness of the claims. *In re Margolis*, 785 F.2d 1029, 228 USPQ 940 (Fed. Cir. 1986)." MPEP §716.01(a) (Eighth Ed., Rev. Aug. 6, 2007).

¹⁹"35 U.S.C. 112 requires that the applicant shall particularly point out and distinctly claim the subject matter which she regards as his or her invention. The portion of the application in which she does this forms the claim or claims. This is an important part of the application, as it is the definition of that for which protection is granted." MPEP §608.01(k) (Eighth Ed., Rev. Aug. 6, 2007).

²⁰35 U.S.C. §41.

²¹U.S. Patent and Trademark Office, *available at* <<http://www.uspto.gov/web/offices/com/strat21/action/sr1fr1.htm>>.

²²"An information disclosure statement filed in accordance with the provisions of 37 C.F.R. 1.97 and 37 C.F.R. 1.98 will be considered by the examiner assigned to the application. The requirements for the content of a statement have been simplified in the rules, to encourage individuals associated in a substantive way with the filing and prosecution of a patent application to submit information to the Office so the examiner can evaluate its relevance to the claimed invention. The procedures for submitting an information disclosure statement under the rules are designed to encourage individuals to submit information to the Office promptly and in a uniform manner. These rules provide certainty for the public by defining the requirements for submitting information disclosure statements to the Office so that the Office will consider information contained therein before a patent is granted." MPEP §609 (Eighth Ed., Rev. Aug. 6, 2007).

²³The Examiner is to search those areas where the invention would most likely be found in the prior art.

²⁴"When determining the field of search, three reference sources must be considered—domestic patents (including patent application publications), foreign patent documents, and non-patent literature (NPL)." MPEP §904.02. Also see discussion on searching patents in Chapter 3.

1. *Pre-First Action Interview [New Topic]*

Providing an interview prior to the first office action can maximize your success with the Examiner by providing the Examiner with a better understanding of the invention, bring the closest prior art to the attention of the Examiner, and allow the Examiner to provide a more focused search, which may reduce the prosecution time of the application. This permits an earlier “meeting of the minds” between applicant and the Examiner, which may lead to higher quality, prompter, and an earlier allowance of your application.

In continuing and substitute applications, interviews are ordinarily granted prior to the first office action. In other cases, an interview before the first office action is encouraged where the Examiner determines that such an interview would advance prosecution of the application.

When an applicant requests an interview before first office action in a noncontinuing or nonsubstitute case, granting of the interview is within the discretion of the Examiner. The Examiner may request a paper that includes a general statement of the state of the art at the time of the invention, along with an identification of no more than three references that applicant believes to be the “closest” prior art. In addition, applicant would need to provide an explanation of how the broadest claim patentably distinguishes from the closest prior art.²⁵

2. *First Action Interview Pilot Program [New Topic]*

Effective April 28, 2008, the U.S. Patent & Trademark Office (PTO) initiated a First Action Interview Pilot Program, which can make granting a first action interview with the Examiner nondiscretionary. To participate in the program, an applicant must file the request using EFS-Web. The application is not advanced out of turn. The request must be filed at least one day before a first Office Action on the merits of the application appears in the Patent Application Information Retrieval (PAIR) system. If a restriction is required, the Examiner will contact the Applicant and follow the procedure for telephone restriction practice.²⁶ When the application is taken up for examination, the Examiner will conduct a prior art search and provide applicant with a Pre-Interview communication, which includes citations to prior art references from the search and an identification of potential rejections or objections if any claim is not allowable. Applicant then has 30 days to schedule the interview and file a proposed amendment or remarks. A “proposed amendment” means that the Applicant has no right to have the amendment entered after the Pre-Interview communication has been sent out. Entry of the amendment is solely within the discretion of the Examiner. The Office may enter the amendment if it is clearly limited to cancellation of claims, adoption of Examiner suggestions, placement of the Application in prima

²⁵MPEP §713.02.

²⁶MPEP §812.01.

facie condition for allowance, and/or correct informalities. Applications filed on or before September 1, 2005, that have not received a first action on the merits, that are classified in class 709 (Electrical Computers and Digital Signal Processing Systems) and assigned to an Art Unit in Working Group 2140 or 2150 are eligible for the Pilot. Also eligible for the Pilot are applications filed on or before November 1, 2006, which have not received a first action on the merits, that are classified in Class 707 (Data Processing: Database and File Management or Data Structures) and assigned to an Art Unit in Working Group 2160.²⁷

C. Protecting Your Client's Best Interests

Maximizing your success with the Examiner does not always mean giving the Examiner what she wants. It is of paramount importance that the client's best interests be kept in mind. It is your legal duty to be a zealous advocate for your client.²⁸ The client is the one paying for your services and deserves the best representation that you can provide. The client obviously wants a high-quality examination leading to a promptly issued, valid patent. The desired goal is to obtain the broadest scope of protection that the law allows to enable the client to get the best return on investment for her innovation. However, this requires a good understanding of the client's financial position to effectively devise the best strategy consistent with her budget. The client is always cost conscious and wants to obtain the most patents within her allotted budget. The client usually wishes to obtain as many patents as possible to attract investors for the company and to increase licensing opportunities, which can generate revenues for reinvestment in applied research and development. The early examination and allowance of the client's patent applications provide the best opportunity for the client to achieve her business objectives. In an ideal world, the client would like to see her applications avoid protracted examination and the necessity of appeals to obtain the desired broad scope protection and exclusive rights.²⁹ Therefore, you should never lose sight of the "bottom line" when formulating your strategy for application preparation and prosecution.

Because the PTO classifies inventions into more than 400 categories³⁰ that are assigned to the more than 6055 patent Examiners situated in the nine technology centers,³¹ the fate of the application may be greatly af-

²⁷See USPTO *Official Gazette* (Apr. 27, 2004) .

²⁸37 C.F.R. §10.84.

²⁹It is recognized that for pharmaceutical inventions that have their greatest value at the end of the patent term, patent term extension or adjustment under 35 U.S.C. §§154–156 may substantially benefit the patent owner. However, for inventions in the electrical arts, delays in patent issuance may be harmful.

³⁰See <<http://www.uspto.gov/web/patents/classification/selectnumwithtitle.htm>>.

³¹Bruce Kisliuk, Acting Deputy Commissioner for Patent Operations for Technology Centers 2600 and 2800, AIPLA Presentation (May 2009).

ected by how the claim subject matter is classified in the U.S. patent classification system. Its classification determines how the PTO will assign it to a particular Examiner, in a specified art unit, in a given technology center.³² Applications are classified based upon the most comprehensive claim, in a hierarchy defined by the principles of the U.S. patent classification system.³³ Through this system of application assignment, the application may find its way to a chemical, electrical, or mechanical patent Examiner, each of whom may have different styles of patent examination.³⁴ Also, depending upon the backlogs of work in each technology center, the delay in a first examination varies widely from 29.1 months in TC 2800 (Semiconductor, Electrical, Optical Systems) to 48.3 months in TC 2400 (Networking, Multiplexing, Cable and Security).³⁵ See Exhibit 9.1.

Although this might be good for inventions in fields of technology where the value of the patent is greatest at the end of the patent term, such as in the pharmaceutical or biotechnology arts, it may be disastrous for inventions in fast-moving and short-lived technologies where the greatest value of the patent will be early in its 20-year patent term. Careful claim drafting can influence where the application will be classified and examined. Consequently, knowledge of the patent pendencies for each field of technology at the PTO is important when strategizing how claims will be drafted.

1. Preappeal Brief Review Request [New Topic]

On July 12, 2005, the PTO instituted a Preappeal Brief Conference Pilot Program³⁶ that allows applicants to request that a panel of Examiners formally review the legal and factual basis of the rejections, prior to the filing of an appeal brief. The goals of the program are to identify clearly improper rejections based on errors in facts or to identify the omission of elements required to establish a prima facie rejection. This Pilot is of value to applicants who believe that the rejections of record are clearly improper, rather than being based upon an interpretation of claims or prior art teachings. To request a panel review, applicant must file the request with a Notice of Appeal and before the filing of an appeal brief. The Request may not exceed a total of five pages,³⁷ and should concisely point out that a limitation is not met by the reference or that there is no proper motivation for making the modification in an obviousness rejection under 35 U.S.C. §103. Applicants can maximize success with the Examiner by overcoming an unreasonable rejection without having to go through the expense of an appeal. Approximately 1016 conferences were held during January and Feb-

³²MPEP §903.08(b).

³³MPEP §903.02.

³⁴Examiners in the chemical arts are more prone to use more restriction requirements and apply 35 U.S.C. §112, first paragraph requirements more rigorously to the claimed invention.

³⁵Kisliuk, AIPLA Presentation.

³⁶See <<http://www.uspto.gov/web/offices/com/sol.og.2005/week28/patbref.htm>>.

³⁷The five pages includes the signature page.

Exhibit 9.1**Patent Pendency – FY 2008 and FY 2009**

| Technology Center | Average 1 st Action Pendency (months) ¹ 4 th Quarter FY08 | Average 1 st Action Pendency (months) ¹ 2 nd Quarter FY09 | Average Total Pendency (months) ² 4 th Quarter FY08 | Average Total Pendency (months) ² 2 nd Quarter FY09 |
|-----------------------------------------------------------|-----------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------|
| 1600 - Biotechnology and Organic Chemistry | 19.9 | 24.3 | 34.8 | 34.8 |
| 1700 - Chemical and Materials Engineering | 27.5 | 27.3 | 36.3 | 37.3 |
| 2100 - Computer Architecture Software | 30.8 | 30.0 | 42.4 | 41.0 |
| 2400 - Networking, Multiplexing, Cable, and Security | | 36.0 | | 48.3 |
| 2600 - Communications | 32.5 | 34.1 | 43.6 | 42.6 |
| 2800 - Semiconductor, Electrical, Optical Systems | 19.5 | 20.6 | 28.2 | 29.1 |
| 3600 - Transportation, Construction, Electronic Commerce | 24.3 | 25.1 | 34.8 | 34.5 |
| 3700 - Mechanical Engineering, Manufacturing and Products | 24.7 | 25.9 | 32.7 | 34.7 |
| UPR Total 4 th Quarter FY 2008 | 25.6 | 26.9 | 32.2 | 33.7 |

¹ "Average 1st action pendency" is the average age from filing to first action for a newly filed application.

² "Average total pendency" is the average age from filing to issue or abandonment of a newly filed application.

bruary 2009. The percentage of time that prosecution was reopened was 40 percent. Accordingly, this procedure is not for everyone.³⁸

§9.02 Items to Consider Before Preparing the Patent Application**A. Assessing Inventorship**

Before preparing the patent application, it is important to identify the true inventors³⁹ and ask them whether they have done anything that may have led to disclosure of the invention to the public.⁴⁰ If there are multiple

³⁸Statistics provided by Robert W. Bahr, Acting Deputy Commissioner for Patent Examination Policy, Office of the Deputy Commissioner for Patent Operations (May 2009).

³⁹"It is desirable to ask questions about inventorship. Who is the proper inventor? Are there disputes or possible disputes about inventorship? If there are questions, call them to the attention of the U.S. Patent and Trademark Office." MPEP §2004.

⁴⁰Many attorneys, both corporate and private, are using letters and questionnaires for applicants and others involved with the filing and prosecution of the application and checklists for themselves and applicants to ensure compliance with the duty of disclosure. The letter generally explains the duty of disclosure and what it means to the inventor and assignee. The questionnaire asks the inventor and assignee questions about

- the origin of the invention and its point of departure from what was previously known and in the prior art,
- possible public uses and sales,
- prior publication, knowledge, patents, foreign patents, etc. The checklist is used by the attorney to ensure that the applicant has been informed of the duty of disclosure and that the

inventors, each one must have made a contribution individually or jointly to the subject matter that will be disclosed in the application. The inventors may be joint inventors even though they did not physically work together or at the same time or make the same type or amount of contribution.⁴¹ Because the inventor is in the best position to know the invention, you must obtain a comprehensive disclosure of the invention from her. When doing so, ask the inventors the names of other researchers working in their same field. This will allow the representative to obtain and access copies of the published papers and presentations, as well as published applications and granted patents authored by known researchers working in the same field as the inventors, both in the United States and abroad. This will be needed in order to perform an adequate pre-examination search for use in preparing and prosecuting the patent application.

If some part of the invention was disclosed to the public, it is important to ascertain whether that disclosure was more than one year ago—as that would result in barring patentability of the invention.⁴² Also, it is important to determine whether the inventor intends to make any public disclosure in the near future. The public disclosure may be in the form of a public use or sale of the invention or its description in a printed publication.⁴³ The latter information is especially crucial since patent Examiners may perform author searches of nonpatent literature to determine the extent of the inventor's prior published work that may be available as prior art. The best rule is to avoid surprises of this sort.

Additionally, due diligence in determining who the correct inventors are will avoid the unfortunate circumstance where a true, but unnamed, inventor comes to light after a patent issues and offers a license to a competitor. Such an act would nullify the patent owner's ability to effectively enforce the patent against a competitor for accused acts of infringement that occur after the competitor has taken a license from a true inventor who was not named in the patent.⁴⁴

attorney has inquired of and cited material prior art. The use of these types of aids would appear to be most helpful, though not required, in identifying prior art and may well help the attorney and the client avoid or more easily explain a potentially embarrassing and harmful 'fraud' allegation.

MPEP §2004.

⁴¹35 U.S.C. §116.

⁴²35 U.S.C. §102(b).

⁴³"It may be desirable to submit information about prior uses and sales even if it appears that they may have been experimental, not involve the specifically claimed invention, or not encompass a completed invention. *See* Hycor Corp. v. The Schlueter Co., 740 F.2d 1529, 1534–37, 222 USPQ 553, 557–559 (Fed. Cir. 1984). *See also* LaBounty Mfg., Inc. v. U.S. Int'l Trade Comm'n, 958 F.2d 1066, 22 USPQ2d 1025 (Fed. Cir. 1992)." MPEP §2004.

⁴⁴*Ethicon, Inc. v. United States Surgical Corp.*, 135 F.3d 1456, 45 USPQ2d 1545 (Fed. Cir. 1998).

B. Duty of Disclosure

Individuals associated with the filing or prosecution of a patent application have a duty of candor and good faith in dealing with the PTO. The duty includes an obligation to disclose all information known to be material to patentability for each pending claim in an application until that claim is cancelled or withdrawn from consideration or the application becomes abandoned. Information material to patentability is defined in 37 C.F.R. §1.56(b) as follows:

- (b) Under this section, information is material to patentability when it is not cumulative to information already of record or being made of record in the application, and
- (1) It establishes, by itself or in combination with other information, a *prima facie* case of unpatentability of a claim; or
 - (2) It refutes, or is inconsistent with, a position the applicant takes in:
 - (i) Opposing an argument of unpatentability relied on by the Office, or
 - (ii) Asserting an argument of patentability. A *prima facie* case of unpatentability is established when the information compels a conclusion that a claim is unpatentable under the preponderance of evidence, burden-of-proof standard, giving each term in the claim its broadest reasonable construction consistent with the specification, and before any consideration is given to evidence which may be submitted in an attempt to establish a contrary conclusion of patentability.⁴⁵

Those bound by the duty of disclosure include each inventor, attorney, or agent preparing or prosecuting the application as well as anyone else substantively involved in the preparation or prosecution of the application.⁴⁶

When discussing with the inventors their duty of disclosure obligation, you should ascertain what U.S. patents and published applications, foreign patents and publications, and nonpatent literature are known to them that are closely related to their invention. If they are aware of relevant non-English language documents that should be cited to the Examiner in an information disclosure statement, they should be asked whether an English language translation is readily available.⁴⁷ If there are related applications that have previously been filed, they should be identified and brought to the Examiner's attention through the filing of an information disclosure statement, because you cannot assume that the Examiner is necessarily aware of other copending related applications that are material to patentability, no matter how diligent and well-informed the Examiner may be.⁴⁸

⁴⁵37 C.F.R. §1.56(b).

⁴⁶37 C.F.R. §1.56(c).

⁴⁷37 C.F.R. §1.98(a)(3)(ii).

⁴⁸Do not rely on the examiner of a particular application to be aware of other applications belonging to the same applicant or assignee. It is desirable to call such applications to the attention of the examiner even if there is only a question that they might be 'material to patentability' of the application the examiner is considering. *See Dayco Prod., Inc. v. Total Containment, Inc.*, 329 F.3d 1358, 1365-69, 66 USPQ2d 1801, 1806-08 (Fed. Cir. 2003) (contrary decision of another examiner reviewing substantially similar claims is 'material'; copending application may be 'material' even though it cannot result in a shorter patent term, when it could affect the rights of the patentee to assign the issued patents). It is desirable to be particularly careful that prior art or other information in one

Disclosing only the existence of a copending case might not be a sufficient disclosure. In *McKesson Information Solutions, Inc. v. Bridge Medical, Inc.*,⁴⁹ McKesson never told the Examiner that claims very similar to those in the application before the Examiner were added to a copending application and that the Examiner in the copending application had applied prior art to reject the very similar claims. The rejection of the similar claims in the copending application were rejected over references not of record in the application before the Examiner. McKesson never informed the Examiner of the references relied on by the Examiner in the copending application, and had advised the Examiner that there was no prior art for the key feature in the claims, even though McKesson was aware of the prior art and the rejection of the claims in the copending application. Thus, the fact that McKesson twice advised the Examiner of the existence of the copending application, the Court found inequitable conduct to have occurred.

Although there is no obligation to perform a pre-examination search,⁵⁰ many times the inventors have picked up information at conventions, visits to other companies, and in-house technical literature that not only constitutes prior art but might be considered important to the patent Examiner in making a patentability determination. Again, this type of information should be submitted to the PTO even though the attorney, agent, or inventor doesn't necessarily consider it material to patentability. It is best left to the Examiner, rather than the applicant, to be the ultimate arbiter of materiality.⁵¹

C. Pre-examination Prior Art Search

To ensure the preparation of a high-quality patent application, and especially the drafting of original claims that will not undergo narrowing amendments for reasons of patentability⁵² during prosecution, it is impor-

application is cited to the examiner in other applications to which it would be material. Do not assume that an examiner will necessarily remember, when examining a particular application, other applications which the examiner is examining, or has examined. A 'lapse on the part of the examiner does not excuse the applicant.' *KangaROOS U.S.A., Inc. v. Caldor, Inc.*, 778 F.2d 1571, 1576, 228 USPQ 32, 35 (Fed. Cir. 1985)." MPEP §2004.

⁴⁹487 F.3d 897 (Fed. Cir. 2007).

⁵⁰*FMC Corp. v. Hennessy Indus., Inc.*, 836 F.2d 521, 5 USPQ2d 1272 (Fed. Cir. 1987).

⁵¹"When in doubt, it is desirable and safest to submit information. Even though the attorney, agent, or applicant doesn't consider it necessarily material, someone else may see it differently and embarrassing questions can be avoided. The court in *U.S. Indus. v. Norton Co.*, 210 USPQ 94, 107 (N.D.N.Y. 1980) stated 'In short, the question of relevancy in close cases, should be left to the examiner and not the applicant.' See also *LaBounty Mfg., Inc. v. U.S. Int'l Trade Comm'n*, 958 F.2d 1066, 22 USPQ2d 1025 (Fed. Cir. 1992)." MPEP §2004.

⁵²*Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd.*, 535 US 722, 62 USPQ2d 1705 (2002), *on remand*, 304 F.3d 1289, 64 USPQ2d 1698 (Fed. Cir. 2003) (en banc) ("[A] narrowing amendment made to satisfy any requirement of the Patent Act may give rise to an estoppel."). A patent owner who surrenders subject matter through a narrowing amendment of claims during prosecution of the application may be precluded under the doctrine of prosecution history estoppel from proving infringement under the doctrine of equivalents in an enforcement action against an accused infringer who does not literally infringe the patent claims. 35 U.S.C. §271(a).

tant to conduct a patentability search before drafting a patent application. This is true even where the inventors have a good understanding of the state of the art in their field of expertise. The patentability search may uncover patents and technical literature that is not being commercialized and may be unknown to the inventors. Most importantly, look to published works of the client's competitors. These works may include publicly available information such as brochures, white papers, and operating manuals. Additionally, reviewing the patent portfolios of competitors will help assess relative strengths and weaknesses of both the client and the competitors. It will help the client design around claims in competitors' patents. A comprehensive pre-examination search should take into account claims that might be drafted that are of varying scope from the broadest applicant believes she is entitled to the most detailed she would be willing to accept.⁵³

1. Electronic Searching [New Topic]

Searches can be performed at the PTO search room; the Patent & Trademark Depository Libraries (PTDLs); and at the PTO,⁵⁴ EPO,⁵⁵ and JPO⁵⁶ Web sites. Documents that can be searched include U.S. patents and published applications, foreign patent documents, nonpatent literature, including Internet searches as well as searches of trade publications and databases. Search templates are available⁵⁷ at the PTO Web site. The current requirements for searches conducted by the Examiners can be found in the MPEP.⁵⁸

These search templates can be useful to practitioners in formulating their own pre-examination searches or for the submission of an Accelerated Examination Support Document filed as part of a Petition to Make Special for accelerated examination.

D. Electronic Filing (EFS-Web and PAIR) [New Topic]

In September 2004, the PTO published a legal framework for the use of an electronic filing system.⁵⁹ In 2005, the result was that 2.2 percent of applications were filed electronically. In March 2006, the PTO announced a new Web-enabled filing system EFS-Web that allows PDF-based submission of patent applications.⁶⁰ In FY 2006, the percentage of patent applica-

⁵³MPEP §904.03.

⁵⁴See <<http://www.uspto.gov>>.

⁵⁵See <<http://ep.espacenet.com>>.

⁵⁶See <<http://www.jpo.go.jp>>.

⁵⁷See <<http://www.uspto.gov/web/patents/searchtemplates/searchtemplates.htm>>.

⁵⁸MPEP §904.02.

⁵⁹OG Notice of Sept. 14, 2004.

⁶⁰See John Doll, Commissioner for Patents, ABA 2007 Administrative Law Conference (Oct. 27, 2007).

tions that were electronically filed rose to 14.1 percent. A much greater increase occurred in FY 2007 where 49.3 percent of all applications were electronically filed. During FY 2008, 72.1 percent of patent applications were filed using EFS-Web.⁶¹ Benefits of the system include immediate acknowledgement of the filing and improved ability to track the status of applications through PAIR. In addition, by eliminating paper and delays resulting from manual handling, quality and timeliness is improved. Applicants can file applications anytime and anywhere with an Internet connection. Documents need to be scanned into an image PDF file before filing. An advantage of using EFS-Web is that drawings can be scanned at a higher resolution before filing. This will benefit the Examiner in cases with complex drawings. In addition, filing using EFS-Web provides an Applicant with a 25 percent discount on the Application size fee.⁶² Success with the Examiner—who will have ready access to the application in electronic form and a more complete file wrapper—can be maximized through electronic filing of applications.

When applications are filed using EFS-Web, they are included in an image file wrapper (IFW) and are put into the Patent Application Locating and Monitoring System (PALM). In addition, papers filed with the PTO during prosecution of the patent application can be filed electronically and documents sent out by the PTO can be viewed and printed from the Public and Private Patent Application Information Retrieval Systems (Public and Private PAIR).

E. Accelerated Examination [New Topic]

Effective August 26, 2006, the PTO has established procedures for the acceleration of examination of patent applications,⁶³ with a goal of providing a final disposition of the application within 12 months or less.⁶⁴ A supplement to program requirements,⁶⁵ published in the *Federal Register* notice dated June 26, sets forth the requirements for petitions to make special under the accelerated examination procedures. To qualify for the accelerated examination program, an applicant must submit the petition and fee (if a fee is required) with respect to a complete application filed under 35 U.S.C. §111(a). The application must have three or fewer independent claims and no more than 20 claims in total. If the application has been filed with more than one claimed invention, applicant must be willing to elect over the telephone, without traverse. In addition, applicant must agree to a pre-first action interview with the Examiner, conduct a pre-examination search, and provide an examination support document.

⁶¹USPTO Performance and Accountability Report for FY 2008 (Nov. 7, 2008), available at <<http://www.uspto.gov/web/offices/com/annual/2008/index.html>>.

⁶²MPEP §607.

⁶³MPEP §708.02(a).

⁶⁴See <<http://www.uspto.gov/web/patents/accelerated/>>.

⁶⁵See <<http://www.uspto.gov/web/offices/com/sol/notices/71fr36323.pdf>>.

The search should include a classified search of U.S. patents and published applications; a text search that covers the subject matter of the independent claims using terms recognized in the art given their broadest reasonable interpretation; a text search of foreign patent documents that includes the sources required under the PCT minimum documentation requirements⁶⁶ (to the extent available), and a text search of nonpatent literature (NPL) resources from the current PTO search templates.⁶⁷

The Accelerated Examination Support Document (AESD) must contain an Information Disclosure document (IDS). For each reference cited, there must be an identification of all of the limitations of the claims disclosed in the reference. The AESD must include a detailed explanation of how each of the claims are patentable over the references cited, and must include a concise statement of utility of the invention as defined in each of the independent claims. In addition, the AESD must include a showing of where each limitation of the claims finds support under 35 U.S.C. §112, first paragraph, in the specification. If claims are written to invoke 35 U.S.C. §112, sixth paragraph, the showing must also identify the structure, material, or acts in the specification that correspond to each means- or step-plus-function. Finally, the AESD must identify any cited references that may be disqualified under 35 U.S.C. §103(c) as amended under the Cooperative Research and Technology enhancement (CREATE) Act.⁶⁸ From August 25, 2006, through September 30, 2008, 1234 Petitions for Accelerated Examination have been decided; 50 percent were granted. During FY 2008, 68.2 percent of applications undergoing Accelerated Examination were allowed.⁶⁹

Due to the complexities of obtaining approval for accelerated examination, this is obviously not for everyone. However, at times, there will be situations where the applicant will have a strong desire to have prosecution completed within 12 months or less. In this situation, proceeding under the accelerated examination program may be worthwhile. A caveat is that if the patent obtained under the accelerated examination program later goes into litigation, counsel's actions in the search and AESD may be picked apart.

§9.03 Types of Utility Applications

There are three types of national utility applications that can be used by practitioners to establish a U.S. filing date. The first type of application, known as a "provisional application," is a form of internal or domestic priority application.⁷⁰ It enables an applicant to establish a U.S. filing date without starting the 20-year patent term.⁷¹ The second type of application is

⁶⁶See <<http://www.wipo.int/standards/en/part04.html>>.

⁶⁷See <<http://uspto.gov/web/patents/searchtemplates/searchtemplates.htm>>.

⁶⁸Pub. L. No. 108-453, 118 Stat. 3596 (2004).

⁶⁹See <<http://www.uspto.gov/patents/accelerated>>.

⁷⁰35 U.S.C. §§111(b) and 119(e).

⁷¹35 U.S.C. §154(a)(2).

called a “non-provisional application.”⁷² Many people refer to this type of application as a “regular” national application. It is an application that may lead to the granting of a patent, and its filing begins the 20-year patent term.⁷³ The third type of application is a United States origin international application that designates the United States, is filed under the Patent Cooperation Treaty with the receiving office⁷⁴ of the PTO, and is an application for which national stage entry can be delayed for 30 months.⁷⁵ The international filing date of the international application also starts the 20-year patent term.⁷⁶

A. Provisional Applications

Since June 8, 1995, applicants have the option of filing a provisional application for patent. The provisional application system was designed to provide a low-cost, first patent filing in the United States to give U.S. applicants parity with foreign applicants under the Uruguay Round Agreements Act.⁷⁷ Technically, a provisional application is a regular U.S. application. It is filed under 35 U.S.C. §111(b), which allows filing without a formal patent claim, oath or declaration, or any information disclosure statement. A provisional application has a pendency of 12 months after it has been filed. This 12-month pendency period is not extendable. To obtain a patent, therefore, an applicant would file a nonprovisional application within 12 months of the filing date of the provisional application, claim the benefit of the filing date of the earlier-filed provisional application under 35 U.S.C. §119(e), and include a specific reference to the provisional application. An alternative to filing the corresponding nonprovisional application is to convert the provisional application to a nonprovisional within 12 months through filing a grantable petition under 37 C.F.R. §1.53(c)(2). Converting a provisional application to a nonprovisional application usually is not a good idea because it will start the 20-year term of the patent from the original date of the filing of the provisional application.⁷⁸ Normally, the best strategy is to first file a provisional application, then file the nonprovisional application near the end of the 12-month provisional application pendency period to effectively extend the patent term by as much as one year.

A provisional application must identify the names of the inventors, which is normally done in the required cover sheet.⁷⁹ The cover sheet identifies the application as a provisional application and provides the inventors’ names

⁷²37 C.F.R. §1.9(a)(3).

⁷³35 U.S.C. §154.

⁷⁴37 C.F.R. §1.412.

⁷⁵37 U.S.C. §371.

⁷⁶35 U.S.C. §§154(a)(2) and 363.

⁷⁷Pub. L. No. 103-465, 108 Stat. 4986 (codified in scattered sections of 35 U.S.C., among others).

⁷⁸37 C.F.R. §1.53(c)(3).

⁷⁹An application data sheet under 37 C.F.R. §1.76 or a cover letter may be used in place of the cover sheet. 37 C.F.R. §1.53(c)(1).

and addresses, title of the invention, name and registration number of applicant's representative, the document number that the representative has assigned to the application, an address for correspondence, and the name of any U.S. government agency that has a property interest in the application.

Keep in mind that provisional applications are not examined.⁸⁰ The benefits of the provisional application cannot be claimed if the nonprovisional application is not filed within the one-year deadline. Provisional applications cannot claim the benefit of any earlier-filed foreign or domestic application.⁸¹ The disclosure of the invention must be as complete as possible because it is held to the same disclosure requirements as a nonprovisional application.⁸² Finally, payment of the basic filing fee for the provisional application is required in order for any nonprovisional application to be accorded the benefit of the provisional application's filing date.⁸³ If the basic filing fee or the cover sheet is submitted on a date later than when the provisional application was submitted, a surcharge is also required to be paid.⁸⁴ Provisional applications may not be filed for design applications.⁸⁵ Amendments are not permitted unless they are necessary for compliance with applicable regulations.⁸⁶

Use of provisional applications may provide many benefits. It is a low-cost, simplified filing that provides the applicant a year to assess the invention's commercial potential. It establishes a U.S. filing date that permits the applicant to apply a patent pending notice and begins the Paris Convention Priority Year. Members of the Paris Convention are permitted the benefit of the filing date of a first filed national application when filing an application in another Paris member country within 12 months of the filing of the first filed application if the second filed application claims benefit of the filing date of the first filed application. Provisional applications are not published, so the inventor's disclosure is maintained in confidence.⁸⁷ However, if a nonprovisional application is later filed that relies upon the provisional application for priority, the provisional is available on PAIR. Also, note that the effective date of a patent reference based on a provisional application is the filing date of the provisional application.⁸⁸ The provisional application may contain many unrelated inventions, as long as all the proper inventors are named. Also, because it is not examined, the inventions are not subject to restriction. When a nonprovisional application claims more than one independent and distinct invention, the Examiner may insist that the applica-

⁸⁰MPEP §201.04(b).

⁸¹37 C.F.R. §1.53(c)(4).

⁸²37 C.F.R. §1.53(c).

⁸³37 C.F.R. §1.78(a)(4).

⁸⁴37 C.F.R. §1.53(g).

⁸⁵35 U.S.C. §§119(e) and 172.

⁸⁶*Id.*

⁸⁷35 U.S.C. §122(b)(2)(A)(iii).

⁸⁸BPAI Precedential opinion *Ex parte Yamaguchi*, 88 USPQ2d 1606 (Bd. Pat. App. & Inter. 2008).

tion be restricted to only one invention. In such case, the applicant will be asked to elect which of the claimed invention he or she wishes to have examined. Nonelected inventions may then be filed in divisional applications that are not subject to double patenting rejections. This can save applicant money while obtaining an early U.S. filing date. Provisional applications may also be supplemented by further provisional application filings during the Paris Convention Priority Year.⁸⁹

1. Foreign Origin Applications

Provisional applications may be filed by foreign applicants. The provisional application may be filed in a language other than English. The foreign applicant will be given a time limit to provide a verified English translation to enable the claiming of the 35 U.S.C. §119(e) filing date benefit for the later-filed, nonprovisional application.⁹⁰ Filing of the provisional application permits the foreign applicant to gain benefit of the provisional application filing date so that when the nonprovisional application is published, the provisional application's filing date can be used against other applications.⁹¹ Where the foreign applicant intends to file the U.S. nonprovisional application claiming benefit of the foreign priority dates of many earlier-filed counterpart foreign applications, the provisional application may be used to aggregate all of these foreign priority applications into a single provisional application.

2. Restarting the Paris Convention Priority Year

Because there is no copendency requirement between the provisional and nonprovisional applications, the applicant may intentionally abandon the provisional application. Doing so would permit a second provisional application to serve as the basis for a Paris Convention Priority Claim under Article 4(C)(4). However, when preparing the provisional application, the representative must ensure that the disclosure requirements of 35 U.S.C. §112, first paragraph are met.⁹² The representative must make sure that no rights are left outstanding in the first filed provisional application. Namely, the representative must not revive the provisional application, convert it to a nonprovisional application, or claim the benefit of its filing date for another nonprovisional application.

⁸⁹37 C.F.R. §1.78(a)(4).

⁹⁰37 C.F.R. §1.78(a)(5)(iv).

⁹¹MPEP §2136.03.

⁹²*New Railhead Mfg. L.L.C. v. Vermeer Mfg. Co.*, 298 F.3d 1290, 63 USPQ2d 1843 (Fed. Cir. 2002).

B. Nonprovisional Applications

The most common applications filed in the United States are nonprovisional applications under 35 U.S.C. §111(a). Filing of a nonprovisional application starts the 20-year patent term and is examined to determine whether the conditions for patentability have been satisfied.⁹³ Nonprovisional applications can be filed without payment of the basic filing, search, and examination fees, or without an inventor's oath or declaration. However, payment of a surcharge within an extendable time limit set by the Office is required when these missing parts are later submitted.⁹⁴ Nonprovisional applications are searched by the Examiner and examined to determine whether the patent claims are directed to patent-eligible subject matter that is useful, novel, and nonobvious to a person of ordinary skill in the art; sufficiently described to enable a person skilled in the art to practice the invention without undue experimentation; sets forth the best mode contemplated by the inventor for practicing the invention; and describes the invention in such clear, concise, and exact terms so as to particularly point out and distinctly claim the subject matter regarded by the inventor as the invention.⁹⁵ When filing foreign-origin applications, the representative should consider filing preliminary amendments concurrently to enhance success with the Examiner and protect provisional rights. Concurrently filed preliminary amendments will be treated as part of the original application as filed, although the PTO may require that a substitute specification be filed if the amendments go beyond the claims and continuity data.

C. International Applications

The United States is a signatory to the Patent Cooperation Treaty (PCT), found at Appendix T of the Manual of Patent and Examining Procedure, Eighth Edition, Revision 3 (Aug. 2005). As such, the PTO serves as a receiving office, international search and preliminary examining authority, and a designated or elected office for national stage processing.⁹⁶ An international application filed under the PCT that designates the United States has the effect of a regular U.S. national application, except as provided in 35 U.S.C. §102(e).⁹⁷ A benefit of use of the PCT is that all PCT member states must accept international applications that meet the form and content requirements of the PCT articles and rules.⁹⁸ This means that an application for patent, where global protection is sought, may be created once and used many times; this can save applicants time and money.

⁹³35 U.S.C. §131.

⁹⁴35 U.S.C. §111(a)(3) and 37 C.F.R. §1.53(f).

⁹⁵The conditions of patentability are set forth in 35 U.S.C. §§101, 102, 103 and 112.

⁹⁶See 35 U.S.C. §§361–362 and 37 C.F.R. §1.414.

⁹⁷35 U.S.C. §363.

⁹⁸35 U.S.C. §372.

International applications receive an international-style search that results in an international search report published at 18 months from the earliest filing date to which the international application is entitled. Applicants receive a nonbinding written opinion on patentability.⁹⁹ Upon filing a demand for preliminary examination, which may be accompanied by amendments to the application and its claims, an applicant will also receive a nonbinding International Preliminary Examination Report on Patentability (IPRP).¹⁰⁰ Where the applicant receives a positive IPRP, many of the small or medium-size designated or elected offices will grant a national patent without further examination. A positive IPRP may come from two sources: the International Bureau (IB) of the World Intellectual Property Organization (WIPO), when no demand for preliminary examination is filed; or from the International Preliminary Examination Authority, when a demand is filed.

1. Benefits of First Filing

There are many benefits of filing an international application first.¹⁰¹ The international application itself may be used as a priority application under the Paris Convention.¹⁰² More importantly, however, the PCT provides that applicants who enter the national stage may wait up to 30 months from the filing of the international application before seeking national protection—rather than the 12 months given by the Paris Convention.¹⁰³ The international application undergoes search and preliminary examination by one of the 12 international authorities¹⁰⁴ that have the competency to provide international searches and nonbinding patentability opinions. In particular, as previously mentioned, small and medium national offices may grant patents without further examination when one of these international authorities issues a positive report on patentability. A positive report on patentability suggests that the claimed invention is novel, has inventive step, and is adequately disclosed.

2. Concurrent Processing With Nonprovisional Application

In the United States another benefit occurs when both the international application and a corresponding nonprovisional application are pending in the PTO. If the nonprovisional application was filed prior to or concurrently with the international application, it is the policy of the PTO to concurrently search the international application and examine the nonprovisional appli-

⁹⁹See PCT Rules 43 and 43^{bis}.

¹⁰⁰See PCT Rules 53, 66 and 70.

¹⁰¹See <http://www.wipo.int/pct/en/basic_facts/basic_facts.pdf> for a discussion of the basic facts and benefits of the use of the PCT.

¹⁰²See 35 U.S.C. §365.

¹⁰³See PCT Articles 22 and 39.

¹⁰⁴See <<http://www.wipo.int/pct/guide/en/index.html>> for a listing of the ISA and IPEA.

cation. Because PCT Rules 43 and 43^{bis} mandate that an international search report be prepared by the international authority within 18 months of publication, concurrent processing of the nonprovisional application in the electrical arts (where first action pendency is about 27¹⁰⁵ months) may serve as an implied petition to make the nonprovisional application “special” so that it is taken out of turn in the normal sequence of examination and given priority examination. Moreover, as the international application has a more liberal unity of invention standard,¹⁰⁶ the corresponding nonprovisional application may not be subject to a restriction requirement; no serious burden exists where search and examination of related inventions is required under the international unity of invention standard.¹⁰⁷ The more liberal unity of invention standard would permit examination of more than one invention in the nonprovisional application. Otherwise, a divisional application may have to be filed and separately prosecuted—leading to increased expense to applicant in the cost of filing, prosecution, issue fee payment, and maintenance fee payments necessary for the divisional application and the patent issuing therefrom.¹⁰⁸ Even where concurrent examination does not take place, there are benefits when the international application designating the United States and corresponding nonprovisional application are concurrently filed. In such case, the European Patent Office (EPO) should be selected by the applicant as the international search authority. The international search results, when made available to the U.S. Examiner in the examination of the counterpart nonprovisional application, may be exploited by the U.S. Examiner to reduce duplication of effort while increasing the comprehensiveness and quality of the search.¹⁰⁹ A stronger patent should result from combining the search efforts into a single examination even if the U.S. Examiner does not give full faith and credit to the work of the EPO Examiner.

§9.04 Preparing the Application

If you have not received a prepared application from a foreign client for filing in the PTO, the best approach in the drafting of a patent application may be drafting a set of claims designed to protect the invention from a variety of perspectives. The audience for the application includes inventors, assignee companies and their officers, the patent Examiner, administrative patent judges, prospective licensees, infringers, and, last but not least, judges and juries. The initially drafted claim set coupled with any invention disclo-

¹⁰⁵Robert W. Bahr, Senior Patent Counsel, Presentation at the ABA 23d Annual Intellectual Property Law Conference (Apr. 10–12, 2008).

¹⁰⁶PCT Rule 13.

¹⁰⁷See MPEP §803.

¹⁰⁸See 35 U.S.C. §41.

¹⁰⁹The EPO Examiners are required to know English, French, and German languages. As such, they have a greater capacity to search European language prior art than U.S. Examiners. Moreover, the database maintained by the EPO is more extensive than the counterpart patent database at the PTO.

sure statement obtained from the inventors, should form the basis of preparation of a high-quality patent application. Never forget to communicate with the client to ensure the quality of the end product. The client should review the detailed description to ensure that nothing critical has been overlooked. It is imperative that the application, particularly the claims, meet the strategic needs of the client. Discuss any potential commercial product with the client and ensure that at least one dependent claim is drawn to the features of the commercial product. If there are multiple inventors, they should identify the claims that they jointly invented. A review of the application by a peer may help identify questions that the patent Examiner might ask. Then, revise the application to eliminate unintended ambiguities. However, as Albert Einstein once said, “[n]ot everything that can be counted counts, and not everything that counts can be counted.”

A. Disclosure—35 U.S.C. §112, First Paragraph

The part of the patent application that sets forth the technical disclosure of the invention is commonly known as the “written description.”¹¹⁰ The description explains how to carry out the invention and serves as an aid to interpreting the meaning of claim terms.¹¹¹ The disclosure of an application contains the drawings as well as the written description of the invention. The specification includes the written description as well as the claims that define the invention. The description should provide an explanation as to how the claimed invention is eligible for patent. Namely, it should establish how the claimed invention produces a concrete, useful, and tangible result.¹¹² Preferably, at least one asserted utility for the claimed invention should be provided, unless the claimed invention has a well-established utility.¹¹³ An invention has a well-established utility, according to Manual of Patent Examining Procedure (MPEP) §2107, if (1) a person of ordinary skill in the art would immediately appreciate why the invention is useful, based on its properties or applications; and (2) the utility is specific, substantial, and credible. The asserted utility should be “specific” to the subject matter claimed. A “substantial” utility is one that demonstrates that the invention has real world value that provides an immediate benefit to the public. A utility that is “credible” will establish that the invention operates as intended. Credibility is assessed from the perspective of one of ordinary skill in the art.¹¹⁴

¹¹⁰*See In re Dossel*, 115 F.3d 942, 944-45, 42 USPQ2d 1881, 1883 (Fed. Cir. 1997).

¹¹¹MPEP §2111.01.

¹¹²*State St. Bank & Trust Co. v. Signature Fin. Group Inc.*, 149 F.3d 1368, 1374, 47 USPQ2d 1596, 1601-02 (Fed. Cir. 1998).

¹¹³MPEP §2107.

¹¹⁴*Id.*

1. *Written Description*

Under 35 U.S.C. §112, first paragraph, the specification must include a “written description” that provides support for the claimed invention. The written description requirement is distinct¹¹⁵ from the enablement requirement, which must teach persons of ordinary skill in the art how to practice the claimed invention without undue experimentation. The written description ensures that the inventor had possession and sufficient characterization of the claimed subject matter, as of the filing date of the application.¹¹⁶ The written description of the invention should set forth the advantages resulting from the invention, including any problems that the invention solves and how it is structurally and functionally distinguishable from the prior art. This may be especially important if the application will serve as a priority document¹¹⁷ for a counterpart application filed in a foreign country. The background section may contain a description of the prior art; however, it may be advisable to omit this from the application and submit such information to the PTO in an Information Disclosure Statement.¹¹⁸

The purpose of the written description requirement is to provide the relevant identifying characteristics of the invention to distinguish it from what already exists in the public domain.¹¹⁹ Although most written description cases concern other issues,¹²⁰ a handful of Federal Circuit opinions have found lack of adequate written description even where the claims were filed as part of an original application. Most of these opinions involved

¹¹⁵*In re Barker*, 559 F.2d 588, 194 USPQ 470 (CCPA 1977), *cert. denied*, 434 U.S. 1064 (1978).

¹¹⁶*Crown Operations Int’l Ltd. v. Solutia*, 289 F.3d 1367, 1379, 62 USPQ2d 1917, 1924 (Fed. Cir. 2002) (“One of our predecessor courts has held the enablement and written description requirements to be separate and distinct . . .”); *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991) (“[W]e hereby reaffirm, that 35 U.S.C. §112, first paragraph, requires a ‘written description of the invention’ which is separate and distinct from the enablement requirement.”); *In re Wilder*, 736 F.2d 1516, 1520, 222 USPQ 369, 372 (Fed. Cir. 1984) (“The description requirement is found in 35 U.S.C. §112 and is separate from the enablement requirement of that provision.”).

¹¹⁷Paris Convention, Article 4. The Paris Convention is not self-executing. Congress has chosen to implement a variation of the Paris Convention Right of Priority in 35 U.S.C. §119.

¹¹⁸*See* MPEP §609.

¹¹⁹*Amgen Inc. v. Chugai Pharm.*, 927 F.2d 1200, 1206, 18 USPQ2d 1016, 1021 (Fed. Cir. 1991).

¹²⁰Lack of adequate written support is most commonly found where claims in a later filed patent application are supported by the description found in an earlier filed foreign patent application or U.S. patent application, the benefit of the filing date of which has been claimed in the later filed application under 35 U.S.C. §119(a) or (e), 35 U.S.C. §120 or 35 U.S.C. §365. Lack of adequate written description may also occur where new or amended claims have been added to a patent application that contain limitations that are not supported by the original patent application as filed. Additionally, in an interference proceeding to determine priority of invention between competing parties for a patent, lack of written description may occur where one or more of the parties to the priority contest do not have claims corresponding to the interference counts that are used determine the right of priority, which find their support in a party’s original or benefit patent application.

inventions in nascent or unpredictable arts.¹²¹ An applicant shows “possession” of the claimed invention by describing the invention using descriptive words, structures, figures, diagrams, and formulas that help define the distinguishing identifying characteristics to show that the applicant was in possession of the claimed invention.¹²² The purpose of this requirement is to distinguish what applicant has invented from the earlier inventions of others.¹²³ The disclosure should sufficiently detail relevant identifying characteristics that may include complete or partial structure, physical or chemical properties, functional characteristics coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics.¹²⁴ For some biological material, identifying characteristics may include a sequence, structure, binding affinity, binding specificity, molecular weight, and length. For example, disclosure of an antigen fully characterized by its structure, formula, chemical name, physical properties, or deposit in a public depository provides an adequate written description of an antibody claimed by its binding affinity to that antigen. Additionally, unique cleavage by particular enzymes, isoelectric points of fragments, detailed restriction enzyme maps, a comparison of enzymatic activities, or antibody cross-reactivity may be sufficient to show possession of the claimed invention.¹²⁵ What is conventional or well-known to one of ordinary skill in the art need not be set forth in great detail.¹²⁶ To support claims to an entire genus in highly unpredictable technologies, a representative number of embodiments should be described.¹²⁷ What constitutes a representative number of embodiments to support a genus is inversely related to the level of skill and knowledge in the art.¹²⁸ For inventions in unpredictable arts, adequate written description that embraces widely variant species is not satisfied by disclosure of only one embodiment.¹²⁹

To maximize your success with the Examiner, it is desirable to provide a “roadmap” in the description to provide antecedent basis for claim limitations whether or not the claim limitations are written in means- or step-plus-function format.¹³⁰ Providing a correlation between claim limitations and the written description will ensure that there is adequate support in the de-

¹²¹*See, e.g.*, *Fiers v. Revel*, 984 F.2d 1164, 25 USPQ2d 1601 (Fed. Cir. 1993); *Amgen, Inc. v. Chugai Pharm. Co.*, 927 F.2d 1200, 18 USPQ2d 1016 (Fed. Cir. 1991).

¹²²*Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997).

¹²³*Amgen v. Chugai Pharm.*, 927 F.2d 1200, 1206, 18 USPQ2d 1016, 1021 (Fed. Cir. 1991).

¹²⁴*Enzo Biochem, Inc. v. Gen-Probe, Inc.* 323 F.3d 956, 63 USPQ2d 1609 (Fed. Cir. 2002).

¹²⁵MPEP §2163.

¹²⁶*Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986).

¹²⁷*In re Curtis*, 354 F.3d 1347, 1358, 69 USPQ2d 1274, 1282 (Fed. Cir. 2004).

¹²⁸MPEP §2163, at 2100–175.

¹²⁹*See LizardTech, Inc. v. Earth Res. Mapping, Inc.*, 424 F.3d 1336 (Fed. Cir. 2005); *Regents of the Univ. of Cal. v. Eli Lilly & Co.*, 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997).

¹³⁰*B. Braun Med., Inc. v. Abbott Labs.*, 124 F.3d 1419, 1424, 43 USPQ2d 1896, 1899 (Fed. Cir. 1997).

scription for claim limitations so as to avoid rejections based on lack of written description, and rejections based upon lack of antecedent basis that would render the claims indefinite.¹³¹ The meaning of every term used in any of the claims should be apparent from the descriptive portion of the specification with clear disclosure as to its significance since the specification is the single best guide to the meaning of a disputed term.¹³² If a term used in the claims is to be given a special meaning, that meaning should be defined in the description.¹³³

2. *Enablement*

According to 35 U.S.C. §112, first paragraph, the specification must “enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use” the claimed invention. An enabled disclosure of the invention is the contractual consideration given by the applicant in exchange for the grant of a patent. The exclusive rights granted by a patent for the duration of the patent term is mutual consideration given by the federal government to the patent owner as its part of the contractual bargain for the knowledge given by the inventor to other persons as to how they may practice the invention.¹³⁴ A recitation of the invention in its broad, intermediate, and narrow aspects, along with a more general description of how to make and use the invention, typically suffices to fulfill the enablement requirement.¹³⁵ However, special precautions should be made to ensure that claims are enabled throughout their entire scope for inventions in unpredictable arts.

To fulfill the enablement requirement the patent applicant must disclose sufficient information so that a skilled artisan would be able to practice the claimed invention without undue experimentation.¹³⁶ *In re Wands*¹³⁷ recites a number of factors that are considered in determining whether a disclosure has sufficient information to demonstrate that the invention can be practiced without undue experimentation, including:

- (1) The quantity of experimentation necessary;
- (2) The amount of direction or guidance provided;
- (3) The presence or absence of working examples;

¹³¹*Budde v. Harley Davidson, Inc.*, 250 F.3d 1369, 1376, 58 USPQ2d 1801, 1806 (Fed. Cir. 2001); *Cardiac Pacemakers, Inc. v. St. Jude Med., Inc.*, 296 F.3d 1106, 1115–18, 63 USPQ2d 1725, 1731–34 (Fed. Cir. 2002).

¹³²*Vitronics Corp. v. Conceptoronic, Inc.*, 90 F.3d 1576, 39 USPQ2d 1573 (Fed. Cir. 1996).

¹³³*Bell Atl. Network Servs., Inc., v. Covad Commc’ns Group, Inc.*, 262 F.3d 1258, 1268, 59 USPQ2d 1865, 1870 (Fed. Cir. 2001).

¹³⁴*See J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int’l Inc.*, 534 U.S. 124, 142, 60 USPQ2d 1865, 1873 (2001) (“The disclosure required by the Patent Act is ‘the *quid pro quo* of the right to exclude.’”) (citing *Kewanee Oil v. Bicron Corp.*, 416 U.S. 470, 484 (1974)).

¹³⁵*See generally In re Cortwright*, 165 F.3d 1353, 49 USPQ2d 1464 (Fed. Cir. 1999).

¹³⁶*See In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

¹³⁷858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988).

- (4) The nature of the invention;
- (5) The state of the prior art;
- (6) The relative skill of those in the art;
- (7) The predictability or unpredictability of the art; and
- (8) The breadth of the claims.¹³⁸

One of the key factors is the predictability of the art. Therefore, meeting the enablement requirement is not usually a problem for inventors in predictable electrical and mechanical fields. However, the biotechnology and pharmaceutical arts, by their very nature, are unpredictable; hence, the courts have been more strict in judging whether a particular disclosure supports a broadly drafted claim in these fields. For example, where structure function correlations may be unknown, small changes to the structure of a molecule could lead to vastly different behaviors.¹³⁹ In another instance, a very minor alteration to a primary structure of a protein sequence could affect its folding properties. If the tertiary structure of the protein dictates its function, the alteration could render it useless for a particular purpose.¹⁴⁰ As such, disclosures within unpredictable arts must provide a sufficient number of illustrations of prophetic or working examples in order to support a broadly drafted claim to a genus because the “breadth of the claims” is relevant to enablement. Fundamentally patented subject matter must be enabled across the full breadth of a particular claim.¹⁴¹ Therefore, it is a best practice when preparing a new application to have the specification show with reasonable specificity how to practice the invention throughout the entire scope of the claim.¹⁴²

Two key points about the enablement requirement must be kept in mind when preparing an application. First, the specification must be enabling *at the time the application is granted*. Subsequent developments in the state of the art will not be considered in determining whether an earlier filed application or patent fulfills the enablement requirement.¹⁴³ Second, patents need not disclose information that is well known or conventional in the art. As patent specifications are directed toward persons of skill in the art, they may represent conventional elements by their names or functional block dia-

¹³⁸858 F.2d at 737, 8 USPQ2d at 1404.

¹³⁹As the C.C.P.A. stated in *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 13, 24 (C.C.P.A. 1970):

In cases involving predictable factors, such as mechanical or electrical elements, a single embodiment provides broad enablement in the sense that, once imagined, other embodiments can be made without difficulty and their performance characteristics predicted by resort to known scientific laws. In cases involving unpredictable factors, such as most chemical and physiological activity, the scope of enablement obviously varies inversely with the degree of unpredictability of the factors involved.

¹⁴⁰See Trilateral Comparative Study at <<http://www.uspto.gov/web/tws/reportfinal.pdf>>.

¹⁴¹*In re Wright*, 999 F.2d 1557, 27 USPQ2d 1510 (Fed. Cir. 1993).

¹⁴²*PPG Indus., Inc. v. Guardian Indus. Corp.*, 75 F.3d 1558, 37 USPQ2d 1618 (Fed. Cir. 1996).

¹⁴³See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993).

grams.¹⁴⁴ The patent specifications need not constitute detailed production documents showing the dimensions, tolerances, and other blueprint parameters.¹⁴⁵

Patent specifications may contain “working examples” when actual test results have been performed by the inventor.¹⁴⁶ Since an actual reduction to practice of the invention is not required to file an application, specifications may also contain simulated or predicted results. This constructive reduction to practice may be in the form of “prophetic examples.” Such “paper experiments” may contribute to enablement so long as they, when practiced, carry out the invention. Prophetic examples must be stated in the present tense to indicate that they were not actually carried out by the inventor.¹⁴⁷

When an invention depends upon the use of living materials, such as cultured cells, words alone within a patent specification might not suffice to enable others to make and use the invention. A deposit of the biological material itself is needed.¹⁴⁸ In such cases, the patent applicant must submit these materials to an approved facility¹⁴⁹ that acts as a biological depository. Upon request, the depositories distribute samples to interested members of the public.¹⁵⁰

The description should be both broad and comprehensive to enable a wide scope of claims as well as to allow a variety of claim interpretations when enforcing the patent. It must be sufficiently flexible to support amendments to claims and address attempted design-arounds by third parties. Preparing a comprehensive disclosure allows the applicant flexibility when the application undergoes examination. It is important that the specification provide a conceptual discussion covering a broad understanding of the invention. Doing so will benefit the patent owner where the future direction the market may take is uncertain. The disclosure must provide support for amended or new claims that might be added and for claims in continuation applications that will better target competitors’ work.¹⁵¹

¹⁴⁴*Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 231 USPQ 81 (Fed. Cir. 1986).

¹⁴⁵*See Christianson v. Colt Indus. Operating Corp.*, 822 F.2d 1544, 3 USPQ2d 1241 (Fed. Cir. 1987).

¹⁴⁶*See Astrazeneca AB v. Mutual Pharm. Co.*, 384 F.3d 1333, 1339, 72 USPQ2d 1726, 1730 (Fed. Cir. 2004) (noting that the specification of the patent-in-suit “provides five detailed working examples of drug formulations embraced by the invention”).

¹⁴⁷*Schering Corp. v. Geneva Pharms., Inc.*, 339 F.3d 1373, 1376 n.1, 67 USPQ2d 1664, 1666 n.1 (Fed. Cir. 2003).

¹⁴⁸37 C.F.R. §1.802.

¹⁴⁹37 C.F.R. §1.803.

¹⁵⁰*Id.* *See also* Elizabeth R. Hall & T. Ling Chwang, *Deposit Requirements for Biological Materials*, 14 *Hous. J. INT’L L.* 565 (1992).

¹⁵¹*Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 41 USPQ2d 1961 (Fed. Cir. 1997).

3. Best Mode

Under 35 U.S.C. §112, first paragraph, the specification must set forth the best mode contemplated by the inventor for carrying out the invention. This requirement is a safeguard for the public against the inventor obtaining a patent while concealing the most advantageous way of practicing the invention.¹⁵² Typically, the best mode requirement compels inventors to disclose information that would have been maintained as a trade secret.¹⁵³ The best mode requirement is distinct from enablement. Enablement objectively focuses upon knowledge of persons of ordinary skill in the art, whereas the best mode requirement concentrates on the subjective knowledge of the inventor.¹⁵⁴ It is important to appreciate that a patent may contain an enabling disclosure yet not describe the best mode.¹⁵⁵ The inventor must disclose the best mode known to her at the time she files a patent application.¹⁵⁶ Information about the invention learned subsequent to the filing date need not be disclosed, even if the application is still pending.¹⁵⁷ The focus is on the scope of the claimed invention and the level of skill in the art.¹⁵⁸ Disclosure of the best mode does not require disclosure of a specific embodiment. In particular for software-related inventions, flowcharts and source code listings are not necessary.¹⁵⁹ In fact, where the application is written in such way that a plurality of embodiments are described, there is no requirement that the applicant point out which of the embodiments is considered to be the best.¹⁶⁰ When conducting examination of an applica-

¹⁵²*In re Nelson*, 280 F.2d 182, 126 USPQ 242 (C.C.P.A. 1960).

¹⁵³*Young Dental Mfg. Co. v. Q3 Special Prods.*, 112 F.3d 1137, 1444, 42 USPQ2d 1589, 1594 (Fed. Cir. 1997) (“The purpose of this requirement is to restrain inventors from applying for a patent while at the same time concealing from the public preferred embodiments which the inventor has, in fact, conceived. . . .”).

¹⁵⁴*Spectra-Physics, Inc. v. Coherent, Inc.*, 827 F.2d 1524, 3 USPQ2d 1737 (Fed. Cir. 1987), *cert. denied*, 484 U.S. 954 (1987).

¹⁵⁵*Bayer AG v. Schein Pharms., Inc.*, 301 F.3d 1306, 1314, 64 USPQ2d 1001, 1006 (Fed. Cir. 2002) (“The best mode requirement is ‘separate and distinct’ from enablement and ‘requires an inventor to disclose the best mode contemplated by him, as of the time he executes his application, of carrying out his invention.’”) (citing *In re Gay*, 309 F.2d 769, 772, 135 USPQ 311, 315 (C.C.P.A. 1962)); *Teleflex, Inc. v. Ficosa North Am. Corp.*, 299 F.3d 1313, 1330, 63 USPQ2d 1374, 1384 (Fed. Cir. 2002) (“[T]his court has repeatedly disclaimed a link between enablement and best mode.”); *Engel Indus., Inc. v. Lockformer Co.*, 946 F.2d 1528, 1533, 20 USPQ2d 1300, 1304 (Fed. Cir. 1991) (“The enablement requirement is separate from that of best mode, and must be separately met.”).

¹⁵⁶*Spectra-Physics*, 827 F.2d at 1535, 3 USPQ2d at 1745 (“The specificity of disclosure required to comply with the best mode requirement must be determined by knowledge of facts within possession of the inventor at the time of filing the application.”).

¹⁵⁷*Engel Indus., Inc. v. Lockformer Co.*, 96 F.3d 1398, 1407, 40 USPQ2d 1161, 1167 (Fed. Cir. 1996) (“The properties of a patented device that are discovered after the patent application has been filed . . . are irrelevant to best mode analysis . . .”).

¹⁵⁸*In re Hayes Microcomputer Prods., Inc. Patent Litig. (Vel-Tel, Inc. v. Hayes Microcomputer Prods., Inc.)*, 982 F.2d 1527, 25 USPQ2d 1241 (Fed. Cir. 1992).

¹⁵⁹*Fonar Corp. v. General Elec. Co.*, 107 F.3d 1543, 41 USPQ2d 1801 (Fed. Cir. 1997), *cert. denied*, 522 U.S. 908 (1997).

¹⁶⁰*Ernsthausen v. Nakayama*, 1 USPQ2d 1539 (Bd. App. & Int. 1985).

tion, Examiners typically do not assess whether the best mode has been presented unless there is evidence to the contrary.¹⁶¹ Despite this understanding of what Examiners consider, a best practice is to obtain information from the inventor about what the inventor believes is the best mode contemplated for practicing the claimed invention. That is what must be disclosed in the written description.

Whether the best mode requirement applies to the invention as expressly claimed, or to the entire disclosure, depends upon the particular circumstances. In general, the inventor's obligation to disclose the best mode relates to the claimed invention. As a result, if an inventor does not expressly claim subject matter, there is ordinarily no disclosure obligation with respect to that subject matter.¹⁶² There is an exception to this rule, however, in cases where the undisclosed subject matter materially affects the claimed invention. In such cases, the best mode requirement applies to the entire invention, even where some of the elements of the invention that are described have not been explicitly claimed.¹⁶³

B. Claims—35 U.S.C. §112, Second Through Sixth Paragraphs

The U.S. patent system is based upon a “peripheral claiming system.” The words of the claims themselves define the boundaries of the personal property right.¹⁶⁴ Like the words in a deed, a claim sets the “metes and bounds” of the right to exclude others from practicing the invention for the life of the patent.¹⁶⁵ Although claims are at the vortex of the patent system, they are difficult to draft properly.¹⁶⁶ Claim drafting requires considerable legal writing skills, as well as technical competence. Claims must recite practical applications of ideas and relationships in a single sentence, while clearly defining the invention. The words of the claim must be carefully chosen to protect the invention in scope that is no more or less than the applicant is entitled.

The second paragraph of 35 U.S.C. §112 requires that the specification “conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.” Although the claims by statute form part of the specification, those persons in the patent field commonly refer to the specification and claims as distinct

¹⁶¹MPEP §2165.03.

¹⁶²*Eli Lilly & Co. v. Barr Labs. Inc.*, 251 F.3d 955, 966, 58 USPQ2d 1865, 1877 (Fed. Cir. 2001).

¹⁶³*Great N. Corp. v. Henry Molded Prods., Inc.*, 934 F.3d 1569, 39 USPQ2d 1997 (Fed. Cir. 1996).

¹⁶⁴*Ex parte Fressola*, 27 USPQ2d 1608 (PTO Bd. 1993), *aff'd*, 17 F.3d 1442 (Fed. Cir. 1993).

¹⁶⁵*See* *Corning Glass Works v. Sumitomo Elec. U.S.A., Inc.*, 868 F.2d 1251, 1257, 9 USPQ2d 1962, 1966 (Fed. Cir. 1989).

¹⁶⁶*See* *Advanced Cardiovascular Sys., Inc. v. C.R. Bard Inc.*, 144 F.R.D. 372, 25 USPQ2d 1354, 1357 (N.D. Cal. 1992).

portions of the patent.¹⁶⁷ The second paragraph of 35 U.S.C. §112 contains a requirement of definiteness, a requirement that claims be sufficiently clear so that others may have notice of the extent of the patentee's exclusive rights.¹⁶⁸ The remaining paragraphs of 35 U.S.C. §112 concern the claims. The third through fifth paragraphs of 35 U.S.C. §112 cover the requirements for dependent claims. Dependent claims recite the contents of an earlier claim and add further limitations.¹⁶⁹ A violation of 35 U.S.C. §112, fourth paragraph, renders a patent invalid just as other violations of other paragraphs of §112 would.¹⁷⁰

In addition, 35 U.S.C. §112, sixth paragraph, provides for statutory "central claiming" through use of "means-plus-function" limitations in claims to a combination of elements.¹⁷¹

"[T]he name of the game is the claim."¹⁷² The claims should be clear and distinctly claim the invention.¹⁷³ They define the property right in terms of the metes and bounds of protection.¹⁷⁴ Although patent applicants enjoy a great deal of discretion in setting forth the language and format of a claim,¹⁷⁵ most practitioners use standardized drafting styles. Among the most notable practices is that each claim is set forth in a single sentence.¹⁷⁶ The one-sentence format contributes to the efficient examination of patent ap-

¹⁶⁷*Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 979, 34 USPQ2d 1321, 1329 (Fed. Cir. 1995) (*en banc*) ("Claims must be read in view of the specification, of which they are a part."), *aff'd*, 517 U.S. 370, 38 USPQ2d 1461 (1996).

¹⁶⁸*Exxon Res. & Eng'g Co. v. United States*, 265 F.3d 1371, 1375, 60 USPQ2d 1272, 1276 (Fed. Cir. 2001) ("Section 112 paragraph 2 of the Patent Act requires that a patent specification conclude with one or more claims 'particularly pointing out and distinctly claiming subject matter which the applicant regards as his invention.' 35 U.S.C. §112, second paragraph. We have stated the standard for assessing whether a patent claim is sufficiently definite to satisfy the statutory requirement as follows: If one skilled in the art would understand the bounds of the claim when read in light of the specification, then the claim satisfies section 112 paragraph 2.").

¹⁶⁹*Bloom Eng'g Co. v. North Am. Mfg. Co.*, 129 F.3d 1247, 1250, 44 USPQ2d 1859, 1861 (Fed. Cir. 1997) ("a dependent claim incorporates by reference all of the limitations of the claim from which it depends.").

¹⁷⁰*Pfizer Inc. v. Ranbaxy Labs. Ltd.*, 457 F.3d 1284, 1292 (Fed. Cir. 2006); *Curtiss-Wright Flow Control Corp.*, 438 F.3d 1374, 1380 (Fed. Cir. 2006).

¹⁷¹*In re Donaldson Co.*, 16 F.3d 1189, 1995, 29 USPQ2d 1845, 1850 (Fed. Cir. 1994) (*en banc*) ("paragraph six [of §112] statutorily provides that one may use means-plus-function language in a claim . . .").

¹⁷²*In re Hiniker Co.*, 150 F.3d 1362, 1369, 47 USPQ2d 1523, 1529 (Fed. Cir. 1998).

¹⁷³35 U.S.C. §112, second paragraph.

¹⁷⁴*Morton Int'l, Inc. v. Cardinal Chem. Co.*, 5 F.3d 1464, 1470, 28 USPQ2d 1190, 1195 (Fed. Cir. 1993).

¹⁷⁵*See Ex parte Tanksley*, 37 USPQ2d 1382, 1386 (PTO Bd. 1994).

¹⁷⁶"While there is no set statutory form for claims, the present Office practice is to insist that each claim must be the object of a sentence starting with 'I (or we) claim,' 'The invention claimed is' (or the equivalent). If, at the time of allowance, the quoted terminology is not present, it is inserted by the Office of Patent Publication. Each claim begins with a capital letter and ends with a period. Periods may not be used elsewhere in the claims except for abbreviations. Where a claim sets forth a plurality of elements or steps, each element or step of the claim should be separated by a line indentation, 37 C.F.R. 1.75(i)." MPEP §608.01(m) (internal citations omitted).

plications.¹⁷⁷ Claims are usually structured in three parts: a preamble, a transition phrase, and a body. When it has been determined that it is material to the invention, a preamble will limit the claim, such as where it is necessary to give “life, meaning and vitality” to the claim.¹⁷⁸ Thus, when drafting a claim, it is preferable to either provide a succinct preamble or to ensure that all limitations recited in the preamble are repeated in the body of the claim.

Section 112, second paragraph, requires that the claims particularly point out and distinctly claim the subject matter which the applicant regards as the invention. This is also known as “claim definiteness.”¹⁷⁹ To be definite a claim must be clearly articulated.¹⁸⁰ The requirement also ensures that once the patent issues, interested parties may also obtain clear notice of what would be necessary to avoid infringement of the claims.¹⁸¹

A claim complies with 35 U.S.C. §112, second paragraph, if it can be readily understood by persons of ordinary skill in the art.¹⁸² Claims are read in light of and consistent with the disclosure of the entire patent. If a claim, when read in view of the remainder of the specification, reasonably apprises skilled artisans of the scope of the patented invention, then the definiteness requirement is satisfied.¹⁸³

Only claims “not amenable to construction” or “insolubly ambiguous” are indefinite.¹⁸⁴ “Some objective standard must be provided in order to allow the public to determine the scope of the claimed invention.”¹⁸⁵ However, a practitioner needs to exercise caution in defining terms in the specification because even if a definition of claim terms can be reduced to words, the claim is still indefinite if a person of ordinary skill in the art cannot translate the definition into meaningfully precise claim scope. In addition, although there is nothing intrinsically wrong with using functional language in claims, in some instances, use of functional language can fail to provide a clear-cut indication of the scope of the subject matter embraced

¹⁷⁷See *Fressola v. Manbeck*, 36 USPQ2d 1211 (D.D.C. 1995).

¹⁷⁸*Catalina Marketing Int'l v. Coolsavings.com, Inc.*, 289 F.3d 801, 62 USPQ2d 1781 (Fed. Cir. 2002).

¹⁷⁹See *Miles Labs., Inc. v. Shandon Inc.*, 997 F.2d 870, 874-75, 27 USPQ2d 1123, 1126 (Fed. Cir. 1993).

¹⁸⁰See *In re Borkowski*, 422 F.2d 904, 909, 164 USPQ 642, 645-46 (C.C.P.A. 1970).

¹⁸¹See *Leeds v. Commissioner of Patents and Trademarks*, 955 F.2d 757, 759, 21 USPQ2d 1771, 1773 (D.C. Cir. 1992).

¹⁸²*Exxon Res. & Eng'g Co. v. United States*, 265 F.3d 1371, 1375, 60 USPQ2d 1272, 1276 (Fed. Cir. 2001) (“Section 112 paragraph 2 of the Patent Act requires that a patent specification conclude with one or more claims ‘particularly pointing out and distinctly claiming subject matter which the applicant regards as his invention.’ 35 U.S.C. §112, second paragraph. We have stated the standard for assessing whether a patent claim is sufficiently definite to satisfy the statutory requirement as follows: If one skilled in the art would understand the bounds of the claim when read in light of the specification, then the claim satisfies section 112 paragraph 2.”).

¹⁸³See *Morton Int'l, Inc. v. Cardinal Chem. Co.*, 5 F.3d 1464, 1470, 28 USPQ2d 1190, 1194 (Fed. Cir. 1993).

¹⁸⁴See *Novo Indus., L.P. v. Micro Molds Corp.*, 350 F.3d 1348, 1353 (Fed. Cir. 2003).

¹⁸⁵*Datamize LLC v. Plumtree Software, Inc.*, 417 F.3d 1342, 1350 (Fed. Cir. 2005).

by the claim, and thus can be indefinite.¹⁸⁶ In *Halliburton*,¹⁸⁷ the court provided some examples of how ambiguities relating to functional limitations could be cured—through the use of quantitative metrics or a formula for calculating a property along with examples that meet the claim limitation—and examples that do not.¹⁸⁸

To maximize success before the Examiner and best protect your client's interests in a subsequent litigation, care should be taken to ensure that the claims are definite by ensuring that some objective standard is provided. If functional limitations are used in the claims, the use of quantitative metrics or formulas may be useful to increase the likelihood that your claims comply with 35 U.S.C. §112, second paragraph.¹⁸⁹

Compliance with the definiteness requirement is a question of law that is reviewed de novo on appeal.¹⁹⁰ Patent claims often contain relative words, such as “about,” “approximately,” “close to,” “substantially equal,” or “closely approximate.” Their use in claims is permitted provided that they reasonably define the invention.¹⁹¹ The specification, the prior art, the prosecution history, and the understandings of persons of ordinary skill in the art identify the precise limits of a relative term.¹⁹² Additionally, applicants are allowed to define their own terms for use in claims since “a patentee is free to be his or her own lexicographer.”¹⁹³

The claims must be well drafted¹⁹⁴ in order to ensure that the desired scope of protection is obtained. Claims should preferably be arranged in order of scope so that the first claim presented is the least restrictive. All dependent claims should be grouped together with the claim or claims to which they refer to the extent practicable. Where separate species are claimed, the claims of like species should be grouped together where possible. Similarly, product and process claims should be separately grouped. Such arrangements are for the purpose of facilitating classification and examination. A well-drafted claim should avoid triggering a rejection for lack of clarity. For example, according to MPEP §2173.05(c), do not set forth a range within a range in a claim. For example, do not recite a temperature

¹⁸⁶*Halliburton Energy Servs. Inc., v. M-1 LLC*, 85 USPQ2d 1654, 1662–63 (Fed. Cir. 2008).

¹⁸⁷*Id.* at 1663.

¹⁸⁸*Id.*

¹⁸⁹*See also IPXL Holdings, LLC v. Amazon.com Inc.*, 430 F.3d 1377 (Fed. Cir. 2005), available at <<http://fedcir.gov/opinions/05-1009.pdf>>; *Microstrategy Inc. v. Business Objects S.A.*, 429 F.3d 1344 (Fed. Cir. 2005).

¹⁹⁰*See Carl Zeiss Stiftung v. Renishaw PLC*, 945 F.2d 1173, 1181, 20 USPQ2d 1094, 1101 (Fed. Cir. 1991).

¹⁹¹*See Andrew Corp. v. Gabriel Elecs.*, 847 F.2d 819, 6 USPQ2d 2010 (Fed. Cir. 1988).

¹⁹²*See Amgen, Inc. v. Chugai Pharm. Co.*, 927 F.2d 1200, 18 USPQ2d 1016 (Fed. Cir. 1991).

¹⁹³*Hormone Research Found., Inc. v. Genentech, Inc.*, 904 F.2d 1558, 1563, 15 USPQ2d 1039, 1043 (Fed. Cir. 1990).

¹⁹⁴“The meaning of every term used in any of the claims should be apparent from the descriptive portion of the specification with clear disclosure as to its import; and in mechanical cases, it should be identified in the descriptive portion of the specification by reference to the drawing, designating the part or parts therein to which the term applies.” MPEP §608.01(o).

between 45 and 78 degrees Celsius, preferably between 50 and 60 degrees Celsius in a single claim. You should present the narrower range in a dependent claim to avoid claim indefiniteness. Examiners like clear claims, and it will substantially improve your relationship with the Examiner if the claims are readily understood. Nevertheless, the scope of protection of a well-drafted claim should be limited only by the prior art and the applicant's disclosure. The claims should target all types of potential infringers, including companies that compete in the same area as the invention, potential customers, third-party users, and remote facilitators such as server and software providers. It is good practice to have a peer review the claims without reading the written description and provide feedback before submitting them to the PTO.

1. Number and Independent or Dependent Type

A diverse set of claims should be drafted to reach the various types of potential infringers. Including a variety of claims in the application increases the likelihood of success in an infringement action. Types of claims to consider include process, product, machine, composition of matter, and means-or step-plus-function claims. For applications in the electrical arts, system and subsystem claims, computer program product claims, data structure, and signal claims¹⁹⁵ should be considered. Process claims are particularly useful since they cover the operation of an invention without restricting it to any particular structure. Product claims are particularly useful in protecting individual system components. Apparatus claims permit targeting of competitors' competing products.

The claims should be drafted in sufficient number to range from broad to narrow scope. The broad claims should be conceptual and extensive enough to cover all embodiments set forth in the written description as well as expected equivalents. Narrower claims are used to protect specific embodiments. The broadest claims will typically be the hardest to obtain and defend. Claims that are generic in application, but narrow in functional scope, may be useful to protect embodiments that are improvements over those of competitors. Claims that relate to the applicant's business and market needs may be useful in seeking protection while avoiding infringement of others' patents. These claims are useful for defensive purposes. Such claims, although still broad in functional scope, are defensible against invalidity attacks. Although narrow claims are least likely to be infringed, they are the most easy to obtain and defend.

Claims may be written in either independent or dependent form. An independent claim defines the invention in self-contained form. A dependent claim refers back to, and incorporates subject matter from, other claims. It further limits another claim or claims by reciting additional subject matter.¹⁹⁶ A claim that depends from a dependent claim should not, according

¹⁹⁵See <<http://www.jmls.edu/JCIL/17/stern.html>>.

¹⁹⁶37 C.F.R. §1.75(c).

to MPEP §608.01(n), be separated by any claim which does not also depend from said “dependent claim.” According to §112, fourth paragraph, a proper dependent claim should “incorporate by reference all the limitations of the particular claim from which it depends.”¹⁹⁷

2. Jepson Claims

A *Jepson* claim has two parts: a preamble that recites what is implied to be admitted prior art, followed by an “improvement” clause that recites in the body of the claim what the applicant regards as the invention.¹⁹⁸ This implication may be overcome where an applicant gives a credible reason for drafting the claim in *Jepson* format or where the preamble of a *Jepson* claim describes applicant’s own work.¹⁹⁹ *Jepson* claims include the transition phrase “wherein the improvement comprises,” or other characterizing phrases.

Jepson claims take their name from *Ex Parte Jepson*.²⁰⁰ One reason why *Jepson* claims remain popular is that foreign patent offices, and in particular the EPO, strongly encourage the use of this claim format.²⁰¹ Many European applicants file the same set of claims in the United States that they did abroad. Foreign applicants are usually well advised to steer clear of the *Jepson* format in the United States to avoid the admitted prior art effect of the preamble.²⁰²

¹⁹⁷35 U.S.C. §112, fourth paragraph.

¹⁹⁸*Dow Chem. Co. v. Sumitomo Chem. Co.*, 257 F.3d 1364, 1381, 59 USPQ2d 1609, 1620 (Fed. Cir. 2001) (“[T]he claimed process is written in *Jepson* format, and describes certain conditions as an improvement over a well known process.”).

¹⁹⁹See *Reading & Bates Constr. Co. v. Baker Energy Res. Corp.*, 748 F.2d 645, 650 (Fed. Cir. 1984); *In re Ehrreich*, 590 F.2d 902, 909–10 (CCPA 1979), and MPEP §2131.

²⁰⁰1917 Comm. Dec. 62, 243 O.G. 525 (Ass’t Comm’r Pat. 1917).

²⁰¹See Arthur L. Plevy, *Some Important Differences Between Patent Practice in Europe and the United States*, 209 N.J. LAW. 40, 41–42 (June 2001).

²⁰²“Drafting a claim in *Jepson* format (i.e., the format described in 37 C.F.R. 1.75(e); see MPEP §608.01(m)) is taken as an implied admission that the subject matter [sic] of the preamble is the prior art work of another. *In re Fout*, 675 F.2d 297, 301, 213 USPQ 532, 534 (CCPA 1982) (holding preamble of *Jepson*-type claim to be admitted prior art where applicant’s specification credited another as the inventor of the subject matter of the preamble). However, this implication may be overcome where applicant gives another credible reason for drafting the claim in *Jepson* format. *In re Ehrreich*, 590 F.2d 902, 909-910, 200 USPQ 504, 510 (CCPA 1979) (holding preamble not to be admitted prior art where applicant explained that the *Jepson* format was used to avoid a double patenting rejection in a copending application and the examiner cited no art showing the subject matter of the preamble). Moreover, where the preamble of a *Jepson* claim describes applicant’s own work, such may not be used against the claims. *Reading & Bates Constr. Co. v. Baker Energy Res. Corp.*, 748 F.2d 645, 650, 223 USPQ 1168, 1172 (Fed. Cir. 1984); *Ehrreich*, 590 F.2d at 909-910, 200 USPQ at 510.” MPEP §2129.

3. *Alternative Claims*

Markush format may be used when no commonly accepted generic term exists to describe alternative aspects of a claimed invention.²⁰³ Markush groups are elements defined by the structure or property common to all members, along with one or more moieties selected from a list of named alternatives.²⁰⁴ The elements recited in the Markush group ordinarily must belong to a recognized physical or chemical class of compounds or to an art-recognized class of compounds. 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 that is mainly responsible for their function in the claimed relationship. Then, it may be inferred from their nature or from the prior art that all of them possess this property. Where a Markush expression is applied only to a *portion* of a chemical compound, the propriety of the grouping is determined by a consideration of the compound *as a whole*, and does not depend on there being commonality of properties in the members of the Markush group. When materials recited in a claim are so related as to constitute a proper Markush group, they may be recited in the conventional manner, or as alternatives. For example, either expression “wherein X is a material selected from the group consisting of A, B, C and D” or “wherein X is A, B, C or D” would be considered proper.²⁰⁵

4. *Means- or Step-Plus-Function*

A functional claim is one that defines an invention in terms of what it does rather than in terms of its structure.²⁰⁶ There is nothing inherently wrong with functional claims.²⁰⁷ However, it has been held that a claim that consists *solely* of a single means for accomplishing a particular task is not “a claim to a combination” as permitted by 35 U.S.C. §112, sixth paragraph, and as such is not enabled.²⁰⁸ Means- or step-plus-function claims cover the corresponding structures, materials, or acts described in the specification and their equivalents. The Federal Circuit has acknowledged the propriety of step-plus-function claims,²⁰⁹ indicating that to invoke §112, sixth para-

²⁰³MPEP §803.02.

²⁰⁴Inventions in metallurgy, refractories, ceramics, pharmacy, pharmacology, and biology are most frequently claimed under the Markush formula. However, purely mechanical features or process steps may also be claimed by using the Markush-style of claiming. *See Ex parte Head*, 214 USPQ 551 (Bd. App. 1981); *In re Gaubert*, 524 F.2d 1222, 187 USPQ 664 (CCPA 1975).

²⁰⁵The PTO published a Notice of Proposed Rulemaking with respect to claims containing alternative language. 72 Fed. Reg. 44,992 (Aug. 10, 2007), *available at* <<http://www.uspto.gov/web/offices/com/sol/notices/72fr44992.pdf>>.

²⁰⁶MPEP §2173.05(g).

²⁰⁷*In re Swinehart*, 439 F.2d 210, 169 USPQ 226 (CCPA 1971).

²⁰⁸*See In re Hyatt*, 708 F.2d 712, 218 USPQ 195 (Fed. Cir. 1983).

²⁰⁹*See O.I. Corp. v. Tekmar Co.*, 115 F.3d 1576, 42 USPQ2d 1777 (Fed. Cir. 1997).

graph, the claim limitation should recite a “step for” performing a specified “function” and should not contain further features that describe how the function is accomplished.²¹⁰ Typically, use of the word “means” triggers a presumption that will invoke the application of means-plus-function claim interpretation.²¹¹ The presumption can be rebutted if (1) the claim language does not link the term “means” to a recited function; or (2) the phrase “means for” is not modified by sufficient structure or material for achieving the specified function.²¹² One advantage of using means- or step-plus-function

²¹⁰*Masco Corp. v. United States*, 303 F.3d 1316, 64 USPQ2d 1182 (Fed. Cir. 2002).

²¹¹*York Prods. Inc. v. Central Tractor Farm & Family Ctr.*, 99 F.3d 1568, 1574, 40 USPQ2d 1619, 1623 (Fed. Cir. 1996); *Greenberg v. Ethicon Endo-Surgery, Inc.*, 91 F.3d 1580, 1584, 39 USPQ2d 1783, 1786-87 (Fed. Cir. 1996).

²¹²While traditional “means for” or “step for” language does not automatically make an element a means- or step-plus-function element, conversely, lack of such language does not prevent a limitation from being construed as a means- or step-plus-function limitation. *See* *Signtech USA, Ltd. v. Vutek, Inc.*, 174 F.3d 1352, 1356, 50 USPQ2d 1372, 1374-75 (Fed. Cir. 1999) (“ink delivery means positioned on” invokes 35 U.S.C. 112, sixth paragraph since the phrase “ink delivery means” is equivalent to “means for ink delivery”); *Al-Site Corp. v. VSI Int’l, Inc.*, 174 F.3d 1308, 1317-19, 50 USPQ2d 1161, 1166-67 (Fed. Cir. 1999) (although the claim elements “eyeglass hanger member” and “eyeglass contacting member” include a function, these claim elements do not invoke 35 U.S.C. 112, sixth paragraph because the claims themselves contain sufficient structural limitations for performing these functions); *Seal-Flex, Inc. v. Athletic Track and Court Constr.*, 172 F.3d 836, 850, 50 USPQ2d 1225, 1234 (Fed. Cir. 1999) (Radar, J., concurring) (“claim elements without express step-plus-function language may nevertheless fall within 112 6 if they merely claim the underlying function without recitation of acts for performing that function. In general terms, the underlying [‘]function’ of a method claim element corresponds to what that element ultimately accomplishes in relationship to what the other elements of the claim and the claim as a whole accomplish. [‘]Acts,’ on the other hand, correspond to how the function is accomplished. If the claim element uses the phrase [‘]step for,’ then §112, 6 is presumed to apply. On the other hand, the term [‘]step’ alone and the phrase [‘]steps of’ tend to show that §112, 6 does not govern that limitation.”); *Personalized Media Commc’ns LLC v. ITC*, 161 F.3d 696, 703-04, 48 USPQ2d 1880, 1886-87 (Fed. Cir. 1998); *Mas-Hamilton Group v. LaGard Inc.*, 156 F.3d 1206, 1213, 48 USPQ2d 1010, 1016 (Fed. Cir. 1998) (“lever moving element for moving the lever” and “movable link member for holding the lever and for releasing the lever” were construed as means-plus-function limitations invoking 35 U.S.C. 112, sixth paragraph since the claimed limitations were described in terms of their function, not their mechanical structure); *Ethicon, Inc. v. United States Surgical Corp.*, 135 F.3d 1456, 1463, 45 USPQ2d 1545, 1550 (Fed. Cir. 1998) (“use of the word means ‘gives rise to a presumption that the inventor used the term advisedly to invoke the statutory mandates for means-plus-function clauses’”); *O.I. Corp. v. Tekmar*, 115 F.3d 1576, 1583, 42 USPQ2d 1777, 1782 (Fed. Cir. 1997) (method claim that paralleled means-plus-function apparatus claim but lacked “step for” language did not invoke 35 U.S.C. 112, sixth paragraph). Thus, absent an express recitation of “means for” or “step for” in the limitation, the broadest reasonable interpretation will not be limited to “corresponding structure and equivalents thereof.” *Morris*, 127 F.3d at 1055, 44 USPQ2d at 1028 (“no comparable mandate in the patent statute that relates the claim scope of non-§112 paragraph 6 claims to particular matter found in the specification”). With respect to the second prong of this analysis, see *York Prods., Inc. v. Central Tractor Farm & Family Ctr.*, 99 F.3d 1568, 1574, 40 USPQ2d 1619, 1624 (Fed. Cir. 1996) (holding that a claim limitation containing the term “means” does not invoke 35 U.S.C. 112, sixth paragraph, if the claim limitation does not link the term “means” to a specific function). It must be clear that the element in the claims is set forth, at least in part, by the function it performs as opposed to the specific structure, material, or acts that perform the function. *See also* *Caterpillar Inc. v. Detroit Diesel Corp.*, 41 USPQ2d 1876, 1882 (N.D. Ind. 1996) (35 U.S.C. 112, sixth paragraph, “applies to functional method claims where the element at issue sets forth a step for reaching a particular result, but not the specific technique or procedure used to achieve

the result.”); *O.I. Corp.*, 115 F.3d at 1582–83, 42 USPQ2d at 1782 (With respect to process claims, “[35 U.S.C. 112, sixth paragraph] is implicated only when *means plus function* without acts are present If we were to construe every process claim containing steps described by an ‘ing’ verb, such as passing, heating, reacting, transferring, etc., into a step-plus-function, we would be limiting process claims in a manner never intended by Congress.” (Emphasis in original.)). However, “the fact that a particular mechanism is defined in functional terms is not sufficient to convert a claim element containing that term into a ‘means for performing a specified function’ within the meaning of section 112(6).” *Greenberg v. Ethicon Endo-Surgery, Inc.*, 91 F.3d 1580, 1583, 39 USPQ2d 1783, 1786 (Fed. Cir. 1996) (“detent mechanism” defined in functional terms was not intended to invoke 35 U.S.C. 112, sixth paragraph). *See also* *Al-Site Corp. v. VSI Int’l Inc.*, 174 F.3d 1308, 1318, 50 USPQ2d 1161, 1166–67 (Fed. Cir. 1999) (although the claim elements “eyeglass hanger member” and “eyeglass contacting member” include a function, these claim elements do not invoke 35 U.S.C. 112, sixth paragraph, because the claims themselves contain sufficient structural limitations for performing those functions). Also, a statement of function appearing only in the claim preamble is generally insufficient to invoke 35 U.S.C. 112, sixth paragraph. *O.I. Corp.*, 115 F.3d at 1583, 42 USPQ2d at 1782 (“[A] statement in a preamble of a result that necessarily follows from performing a series of steps does not convert each of those steps into step plus-function clauses. The steps of ‘passing’ are not individually associated in the claims with functions performed by the steps of passing.”). With respect to the third prong of this analysis, *see* *Seal-Flex*, 172 F.3d at 849, 50 USPQ2d at 1234 (Rader, J., concurring) (“Even when a claim element uses language that generally falls under the step-plus-function format, however, 112 ¶ 6 still does not apply when the claim limitation itself recites sufficient acts for performing the specified function.”); *Envirco Corp. v. Clestra Cleanroom, Inc.*, 209 F.3d 1360, 54 USPQ2d 1449 (Fed. Cir. 2000) (holding “second baffle means” does not invoke 35 U.S.C. 112, sixth paragraph, because the word “baffle” itself imparts structure and the claim further recites the structure of the baffle); *Rodime PLC v. Seagate Tech., Inc.*, 174 F.3d 1294, 1303–04, 50 USPQ2d 1429, 1435–36 (Fed. Cir. 1999) (holding “positioning means for moving” does not invoke 35 U.S.C. 112, sixth paragraph, because the claim further provides a list of the structure underlying the means and the detailed recitation of the structure for performing the moving function removes this element from the purview of 35 U.S.C. 112, sixth paragraph); *Cole v. Kimberly-Clark Corp.*, 102 F.3d 524, 531, 41 USPQ2d 1001, 1006 (Fed. Cir. 1996) (holding “perforation means for tearing” does not invoke 35 U.S.C. 112, sixth paragraph, because the claim describes the structure supporting the tearing function (i.e., perforation)). In other cases, the Federal Circuit has held otherwise. *See* *Unidynamics Corp. v. Automatic Prod. Int’l*, 157 F.3d 1311, 1319, 48 USPQ2d 1099, 1104 (Fed. Cir. 1998) (holding “spring means” does invoke 35 U.S.C. 112, sixth paragraph). During examination, however, applicants have the opportunity and the obligation to define their inventions precisely, including whether a claim limitation invokes 35 U.S.C. 112, sixth paragraph. Thus, if the phrase “means for” or “step for” is modified by sufficient structure, material or acts for achieving the specified function, the USPTO will not apply 35 U.S.C. 112, sixth paragraph, until such modifying language is deleted from the claim limitation. It is necessary to decide on an element by element basis whether 35 U.S.C. 112, sixth paragraph, applies. Not all terms in a means-plus-function or step-plus-function clause are limited to what is disclosed in the written description and equivalents thereof, since 35 U.S.C. 112, sixth paragraph, applies only to the interpretation of the means or step that performs the recited function. *See, e.g.*, *IMS Tech. Inc. v. Haas Automation Inc.*, 206 F.3d 1422, 54 USPQ2d 1129 (Fed. Cir. 2000) (the term “data block” in the phrase “means to sequentially display data block inquiries” was not the means that caused the sequential display, and its meaning was not limited to the disclosed embodiment and equivalents thereof). Each claim must be independently reviewed to determine the applicability of 35 U.S.C. 112, sixth paragraph, even where the application contains substantially similar process and apparatus claims. *O.I. Corp.*, 115 F.3d at 1583–1584, 42 USPQ2d at 1782 (“We understand that the steps in the method claims are essentially in the same language as the limitations in the apparatus claim, albeit without the ‘means for’ qualification. Each claim must be independently reviewed in order to determine if it is subject to the requirements of section 112, ¶ 6. Interpretation of claims would be confusing indeed if claims that are not means- or step-plus function were to be interpreted as if they were, only because they use language similar to that used in other claims that are subject to this provision.”). MPEP §2181.

claims is to avoid surrender of unclaimed subject matter that may occur inadvertently.²¹³ Use of means- or step-plus-function limitations may not preclude application of the doctrine of equivalents, since §112, sixth paragraph, covers equivalents at the time the invention was made whereas equivalents under the doctrine of equivalents cover equivalent functions and later developed equivalents as of the date of infringement.²¹⁴ However, it is crucial that there is an adequate correlation between the corresponding structure material or acts and the means or step-plus-function limitations in order to avoid a rejection for failure to particularly point out and distinctly claim the subject matter that applicant regards as the invention.²¹⁵

5. Product-by-Process Claims

A product-by-process claim is a claim that defines the product by the process by which it is made. For patentability and validity purposes, product-by-process claims are directed to the product and as such are not limited

²¹³Johnson & Johnston Assocs. Inc. v. R.E. Serv. Co., 285 F.3d 1046, 62 USPQ2d 1225 (Fed. Cir. 2002).

²¹⁴Al-Site Corp. v. VSI Int'l, Inc., 174 F.3d 1308, 50 USPQ2d 1161 (Fed. Cir. 1999).

²¹⁵See *JVW Enters., Inc. v. Interact Accessories, Inc.*, 424 F.3d 1324 (Fed. Cir. 2005); *Medical Instrumentation & Diagnostics Corp. v. Elekta AB*, 344 F.3d 1205, 1211 (Fed. Cir. 2003). The proper test for meeting the definiteness requirement is that the corresponding structure (or material or acts) of a means- or step-plus-function limitation must be disclosed in the specification itself in a way that one skilled in the art will understand what structure (or material or acts) will perform the recited function. See *Atmel Corp. v. Information Storage Devices, Inc.*, 198 F.3d 1374, 1381, 53 USPQ2d 1225, 1230 (Fed. Cir. 1999). In *Atmel*, the patentee claimed an apparatus that included a “high voltage generating means” limitation, thereby invoking 35 U.S.C. §112, sixth paragraph. The specification incorporated by reference a non-patent document from a technical journal, which described a particular high voltage generating circuit. The Federal Circuit concluded that the title of the article in the specification may, by itself, be sufficient to indicate to one skilled in the art the precise structure of the means for performing the recited function, and it remanded the case to the district court “to consider the knowledge of one skilled in the art that indicated, based on unrefuted testimony, that the specification disclosed sufficient structure corresponding to the high-voltage means limitation.” *Id.* at 1382, 53 USPQ2d at 1231. The disclosure of the structure (or material or acts) may be implicit or inherent in the specification if it would have been clear to those skilled in the art what structure (or material or acts) corresponds to the means- or step-plus-function claim limitation. See *id.* at 1380, 53 USPQ2d at 1229; *In re Dossel*, 115 F.3d 942, 946–47, 42 USPQ2d 1881, 1885 (Fed. Cir. 1997). If there is no disclosure of structure, material or acts for performing the recited function, the claim fails to satisfy the requirements of 35 U.S.C. §112, second paragraph. *Budde v. Harley-Davidson, Inc.*, 250 F.3d 1369, 1376, 58 USPQ2d 1801, 1806 (Fed. Cir. 2001); *Cardiac Pacemakers, Inc. v. St. Jude Med., Inc.*, 296 F.3d 1106, 1115–18, 63 USPQ2d 1725, 1731–34 (Fed. Cir. 2002) (court interpreted the language of the “third monitoring means for monitoring the ECG signal for activating” to require the same means to perform both functions and the only entity referenced in the specification that could possibly perform both functions is the physician. The court held that excluding the physician, no structure accomplishes the claimed dual functions. Because no structure disclosed in the embodiments of the invention actually performs the claimed dual functions, the specification lacks corresponding structure as required by 35 U.S.C. §112, sixth paragraph, and fails to comply with 35 U.S.C. §112, second paragraph.). MPEP §2181. See also *Maurice Mitchell Innovations, L.P. v. Intel Corp.*, No. 2007-1108 (nonprecedential) (Fed. Cir. Nov. 5, 2007), which held that a party employing a means-plus-function limitation needs to provide a specific example of an embodiment corresponding to the means-plus-function limitation.

by the process steps performed to make the product.²¹⁶ However, the structure implied by the process steps should be considered when drafting product-by-process claims, especially where the product can only be defined by the process steps by which the product is made, or where the manufacturing process steps would be expected to impart distinctive structural characteristics to the final product.

Use of product-by-process claims may be of particular value where the structural, physical, or other characteristic properties of the product are not readily describable. Product-by-process claims may either be products made by a particular process or products identified by a high throughput screening process.²¹⁷

6. *Genus-Species*

Where an application describes multiple embodiments of an invention, it should contain claims drawn to each of the embodiments, which are called species,²¹⁸ as well as claims drawn to the genus that are readable on each of the embodiments. A claim to a genus includes no material element additional to those recited in the species claims and covers the basic organization contained in each of the species.²¹⁹ The distinguishing characteristics

²¹⁶“[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” MPEP §2113.

²¹⁷*Bayer AG v. Housey Pharms., Inc.*, 340 F.3d 1367, 68 USPQ2d 1001 (Fed. Cir. 2003); *AFG Indus. v. Cardinal IG Co.*, 375 F.3d 1367 (Fed. Cir. 2004).

²¹⁸“Claims to be restricted to different species must be mutually exclusive. The general test as to when claims are restricted, respectively, to different species is the fact that one claim recites limitations which under the disclosure are found in a first species but not in a second, while a second claim recites limitations disclosed only for the second species and not the first. This is frequently expressed by saying that claims to be restricted to different species must recite the mutually exclusive characteristics of such species.” MPEP §806.04(f).

²¹⁹In an application presenting three species illustrated, for example, in Figures 1, 2, and 3, respectively, a generic claim should read on each of these views; but the fact that a claim does so read is not conclusive that it is generic. It may define only an element or subcombination common to the several species. It is not possible to define a generic claim with that precision existing in the case of a geometrical term. In general, a generic claim should include no material element additional to those recited in the species claims, and must comprehend within its confines the organization covered in each of the species. For the purpose of obtaining claims to more than one species in the same case, the generic claim cannot include limitations not present in each of the added species claims. Otherwise stated, the claims to the species which can be included in a case in addition to a single species must contain all the limitations of the generic claim. Once a claim that is determined to be generic is allowed, all of the claims drawn to species in addition to the elected species which include all the limitations of the generic claim will ordinarily be obviously allowable in view of the allowance of the generic claim, since the additional species will depend thereon or otherwise include all of the limitations thereof. When all or some of the claims directed to one of the species in addition to the elected species do not include all the limitations of the generic claim, then that species cannot be claimed in the same case with the other species. See MPEP §806.04(d) and §821.04(a).

of the different species must be mutually exclusive. A single species should include limitations found in that embodiment of the invention but not in other embodiments. A claim drawn to the genus is considered to be a linking claim and, as such, is entitled to be examined with the claims drawn to the elected species where the Examiner makes an election of species requirement. Once a claim drawn to the genus is found to be allowable, then all claims that are dependent therefrom that are directed to the various species of the invention will also be allowed, absent §112 problems. Furthermore, any claims that include the allowable features of the claim drawn to the genus will also be allowed, even if not in dependent form. Consequently, it is essential to write claims that cover a genus whenever the application describes multiple embodiments of a single invention. This will avoid having to file unnecessary divisional applications.

7. *Related Inventions*

Many times an application may contain two or more related inventions.²²⁰ If the inventions have a combination/subcombination relationship, to avoid a written restriction requirement by the Examiner, the application should contain an allowable linking claim²²¹ so that both the combination claims and subcombination claims will be examined in the same application. A combination is an organization of elements of which a subcombination forms a component part. Similarly, when presenting product claims, as well as method of making the product and method of using the product claims, the product claims themselves will serve as linking claims. Upon allowance of the product claims, rejoinder of the process claims may be permitted by the Examiner. If the Examiner permits rejoinder after restriction of the application to a single invention, any patent issuing will contain both the product

²²⁰Related inventions include products and methods of making and using them; machines and methods of their use; combinations of elements and subcombinations thereof; subcombinations useable together; a machine and a product made by the machine; and system, subsystem, computer program product and signal claims. MPEP §806.05 *et seq.*

²²¹There 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 application to one would be proper, but presented in the same case are one or more claims (generally called “linking” claims) inseparable therefrom and thus linking together the inventions otherwise divisible. The most common types of linking claims which, if allowed, act to prevent restriction between inventions that can otherwise be shown to be divisible, are

- (A) genus claims linking species claims;
- (B) a claim to the necessary process of making a product linking proper process and product claims;
- (C) a claim to ‘means’ for practicing a process linking proper apparatus and process claims; and
- (D) a claim to the product linking a process of making and a use (process of using).

MPEP §806.05(c) (Eighth Ed., Rev. Aug. 6, 2007).

and process claims.²²² It is desirable to keep as many claims to related inventions in the same application as possible to avoid the cost of the preparation and prosecution of divisional applications, including the additional issue and maintenance fees that can be avoided if the original patent issues with claims to all the related inventions. Additionally, because the 20-year patent term is measured from the date of filing the original application, the later filing of divisional applications after restriction requirements have been made will result in loss of patent term. Consequently, it is essential that linking claims be included in every application to permit examination of claims to related inventions in a single application once the linking claims are allowed. Filing PCT applications that are concurrently searched and examined with their counterpart nonprovisional applications may be the best strategy for keeping related claims together in a single application.

§9.05 Conclusion

Valuable patent rights are valuable assets for patent owners in today's competitive environment. Maximizing your success with the Examiner can go a long way to realizing the goal of achieving these valuable patent rights. Preparing a high quality patent application that will satisfy the Examiner and provide adequate protection for the patentee requires a substantial amount of strategy and careful preparation. In preparing the application, a proper assessment of inventorship is paramount, because failing to name the proper inventors could be disastrous when trying to enforce the patent against accused infringers. Satisfying the duty of disclosure obligation is essential and includes not only obtaining information from the inventors, but also consideration of performing a pre-examination search for use in preparation of the application and especially the original claims. Obtaining a valid but unen-

²²²Where product and process claims drawn to independent and distinct inventions 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. *See* MPEP §806.05(f) and §806.05(h). The claims to the nonelected invention will be withdrawn from further consideration under 37 C.F.R. 1.142. *See* MPEP §809.02(c) and §821 through §821.03. However, if applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims which depend from or otherwise include all the limitations of the allowable product claim will be rejoined. Where the application as originally filed discloses the product and the process for making and/or using the product, and only claims directed to the product are presented for examination, when a product claim is found allowable, applicant may present claims directed to the process of making and/or using the patentable product by way of amendment pursuant to 37 C.F.R. 1.121. In view of the rejoinder procedure, and in order to expedite prosecution, applicants are encouraged to present such process claims, preferably as dependent claims, in the application at an early stage of prosecution. Process claims which depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance. Amendments submitted after final rejection are governed by 37 C.F.R. 1.116. Process claims which do not depend from or otherwise include the limitations of the patentable product will be withdrawn from consideration, via an election by original presentation (*see* MPEP §821.03). Amendments submitted after allowance are governed by 37 C.F.R. 1.312. Process claims which depend from or otherwise include all the limitations of an allowed product claim and which meet the requirements of 35 U.S.C. 101, 102, 103, and 112 may be entered. MPEP §821.04 Rejoinder.

forceable patent must be avoided. When considering the best patent strategy for the client's business needs, serious consideration should be given to use of provisional and international applications.

A well-prepared patent application will demonstrate that the claimed subject matter is eligible for patenting, has practical utility, and provides adequate written description of the invention to support and enable the broadest claims to which the applicant is entitled. The disclosure must be written to enable the claims throughout the entire scope as well as for any particular use claimed. The description should provide a broad spectrum of embodiments of the invention and a full scope of equivalents that were foreseeable at the time the invention was made. It should provide bases for objective indicia of nonobviousness. If the inventors discovered a best mode of carrying out the invention, the disclosure must recite it. Where the invention relates to biological material, serious consideration should be given to the deposit of samples of such biological material in a recognized repository. This may enable applicant to benefit from the doctrine of inherency should a written description problem arise during examination or enforcement of the patent.

Most importantly, claims should be drafted in sufficient number and type to adequately provide exclusive rights for the patent owner against the various types of potential infringers that she may face in the marketplace. When drafting claims to a genus in which generic terms to describe certain claim features do not exist, Markush claim format should be used. Typically, a full range of claims will include both product and process claims. Functional claiming for product claims using means-plus-function limitations should be considered in addition to product claims that are written based upon their structural characteristics and which cover machines or manufactures. Means-plus-function claims are particularly useful in ensuring that adequate claim protection for all disclosed embodiments and their equivalents is obtained. Where products are not readily described by their structural or functional characteristics, product-by-process claims should be employed. When claiming multiple inventions in a single application, it is essential that linking claims be written to enable rejoinder of independent or related inventions after a written restriction requirement has been made by the Examiner. An allowable linking claim will enable the applicant to have more than one invention so linked to be examined in the same application and issued in the same patent. Doing this will save considerable money and preserve the patent term.

Anticipating the Examiner's needs and meeting applicant's expectations is not an easy task. However daunting this task may be, it is a challenge that must be faced in order to be successful.