How to Write a Patent Application

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Chapter One: Introduction and When to File

- Introduction: According to the Supreme Court, a patent application for an invention is "one of the most difficult legal instruments to draw with accuracy" (*Topliff v. Topliff* (1892)) – the drafting process involves describing the invention to those of ordinary skill in the art, and in terms a jury and judge would understand; teaching how to use it, and describing the best mode; claiming the invention broadly to prevent design-around efforts, but narrowly to avoid all prior art; complying with the requirements of the USPTO; and taking all steps necessary to achieve issuance of the patent – the skill in drafting patents is usually acquired on the job, because law school focuses on the substantive law of patents, not the process – this treatise teaches the skill of drafting patent applications, but should be supplemented with other texts and the supervision of experienced patent prosecutors
- Timing of filing an application: Many reasons exist for filing the application as soon as possible – if the filing of a patent application is intended to constitute constructive reduction to practice, an earlier filing date will secure an earlier priority date (the delay caused by a reasonable attorney's drafting docket will not harm a showing of diligence, but an unreasonable delay must be explained) – also, a delayed filing date gives the prior art an opportunity to catch up with the inventor's technology and to create damaging prior art references – the applicant's commercial or publicity activities may also compel the need for a quick filing (especially internationally, where there is no one-year "grace period" as in the U.S.) – also, applications to be filed internationally are subject to other countries' first-to-file systems, so diligence that achieves priority in the U.S. may not be enough to secure international priority – however, it may be wise to delay or withhold filing in light of trade secret issues, the client's budget, the complexity of the invention (where describing it poorly or without substantiating data will invalidate the patent), and the expenses caused by overseas filing
- Techniques for speeding up filing: The broadest claims can be drafted even during the initial meeting with the inventor – the novelty search may be limited, or even skipped, though this might affect the eventual scope of the patent – the drawings can be ordered as early as possible, to be drafted in parallel with the specification; the practitioner and artist can prepare a rough sketch (or use an inventor's drawings), and agreeing up front on reference numbers allows the practitioner to reference them correctly in the specification before the drawings are done – the inventor can file a provisional patent application to secure priority – the application can be filed without the formal papers and inventor's declaration, which can be filed at a later date (though this involves an additional surcharge)

Chapter Two: Parts of a Patent Application

- Overview: In order to obtain a filing date, a patent application must have (1) a complete specification with at least one claim, and (2) all drawings referenced in the specification – if less than all of this is provided, a filing date will not be assigned, and a notice of missing parts will be issued (and the ensuing delay will be deducted from the patent term) – also, within two months of filing, the applicant must file an oath or declaration and payment of the filing fee; these need not be submitted up front to attain a filing date, but a surcharge will be assessed if submitted after filing – the application must also (eventually) include several other documents: a power of attorney form, an assignment (if applicable), a small-entity form (if applicable), an information disclosure statement, a cover sheet, a postcard, and an application data sheet containing bibliographic data – USPTO-approved versions of these forms are available at the USPTO website (and as exhibits in the treatise text)
- Oath or declaration: See 37 CFR §1.63 – the declaration must (a) identify each inventor by name, address, and citizenship, (b) contain an attestation by each inventor verifying the truth of the application and the inventor's involvement in it, and acknowledging the inventor's duty to disclose all material information; and (c) reference any prior filings on which the application claims priority, as well as all foreign applications for the technology not contributing to priority; each reference must specify the application number, country, and date of filing – the declaration must be drafted in a language understood by the inventor – the deadline for filing a declaration is usually the issuance of the patent, but applications claiming priority (including PCT national-phase filings) must have the oath filed within four months of the later filing or sixteen months of the earlier filing – technically, an "oath" differs from a "declaration" by requiring signature before an authorized official like a notary, and by not requiring a notice of criminal penalties for false filing; but almost everyone simply files a declaration at this point
- Power of attorney: See 37 CFR §1.52(c) – this document empowers a patent practitioner to file the application on the inventor's behalf, and should contain a statement to that effect as well as the name, address, and customer number of the law firm – if the invention is being assigned, the power-of-attorney document should be signed by the assignee – in fact, this document isn't required if the practitioner specifies his USPTO registration number in the filed documents, though the USPTO might later request verification; however, it's good practice to have it filed anyway – the power-of-attorney document can be combined with the oath or declaration
- Assignment: See 37 CFR §3.11 and MPEP §302.05 – patents and patent applications are conveyable like personal property, and inventors are often under a duty to assign their invention rights to their employer – this conveyance must be recorded with the USPTO, which can then issue patents in the name of the assignee; also, unrecorded assignments, like real estate deeds, can be void against subsequent assignees who purchased without notice – the assignment should include the title of the invention, names of inventors, the name and address of the assignee, and the date of execution – assignments must be signed by all parties,

and are almost always notarized – a copy of every recordation documents should be submitted to the USPTO, along with a cover sheet containing the same information, and also the total number of patents or patent applications conveyed (with the serial number of each), a correspondence address for USPTO notices about the recordation, and a statement by the submitter vouching for the truth and accuracy of the document

- Small entity form: See 37 CFR §1.27 and MPEP §509.02 – small entities (defined as independent inventors, small business concerns, and nonprofit organizations) receive a 50% discount on many prosecution fees – note: this status is lost if any party assigns or licenses its interests to a non-qualifying assignee – to secure this advantage, the applicant must file an assertion of small entity status, signed by a patent practitioner, inventor, or assignee, along with payment of the reduced filing fee; the penalty of an improper claim to small-entity status is unenforceability of the patent – recommendation: the inventor or assignee should sign this statement, rather than the practitioner, in case of error
- Drawings: See 37 CFR §1.84 and MPEP §608.02 – drawings are essential components of the specification, and where necessary to understand the invention, must be submitted with the specification to receive a filing date (process and composition-of-matter patents are usually deemed not to require a drawing) – drawings must comply with a host of formal requirements, but the application can be filed with informal drawings to be updated later in prosecution; however, the initial drawings must show every feature of the invention specified in the claims
- Specification: See 37 CFR §1.77(a) – the specification describes the invention "in sufficient detail to allow a person of ordinary skill in the art to make and use the invention without undue experimentation" – the specification must also set forth the best mode of using the invention – the specification pages must be numbered centrally (top or bottom), and must be single-sided with L 1" and T/R/B ¾" margins – the specification includes the following parts (if relevant) and in this order:
    - Title of the invention: should be succinct, must be technically accurate
    - Cross-reference to related applications (either parent applications for continuation/CIP/divisional, or a reference to a PCT filing)
    - Statement regarding federally sponsored research or development: see MPEP §310 – inventor must disclose if federal funds were used to develop the invention
    - Reference to a sequence listing
    - Background of the invention: see MPEP §608.01(c) – describes the technical field of the invention, including USPTO patent classification definitions; should not describe the invention, as this might imply that it is prior art
    - Brief summary of the invention: see MPEP §608.01(d) – describes the essence of the inventive concept
    - Brief description of the several views of the drawings: see MPEP §608.01(g) – describes the perspective point and context of the drawings
    - Detailed description of the invention: must include at least one embodiment that one of ordinary skill in the art can use without undue

experimentation, and the best mode known to the inventor at the time of filing – should be short and specific, and should define any terms used in the claims that don't have a common meaning in the art
    - Claims: see CFR §1.75(a) – the application must end with one or more claims, which together define the scope of the invention – should usually begin on a separate page, beginning "I claim," and should be sequentially numbered – usually presented in order from broadest to narrowest
    - Abstract of the disclosure: see MPEP §608.01(b) – the abstract begins on a new page, comprising one paragraph of 150 words or less – should discuss the novel aspects of the invention, but not the merits or applications of the invention – if the application is allowed, the abstract will be reproduced on the cover of the patent
    - Drawings: see above
    - Sequence listing
- Information Disclosure Statement (IDS): Everyone substantially involved in the patent process bears a duty of reporting materially relevant information to the USPTO (37 CFR §1.56(a)) – this reporting is done via the submission of an invention disclosure statement; can be submitted with the application, or within 90 days thereafter to be considered timely – "materiality" exists where the reference, by itself or in combination with other references, might render the invention unpatentable (37 CFR §1.56(b)); since failing this duty can cause patent invalidity, antitrust liability, and professional sanctions, it's good practice to err on the side of submitting questionable documents
- Foreign filing claim: A U.S. patent application can benefit from a foreign filing date (35 USC §§119 and 365) – requirements: unity of inventors, unity of invention, reciprocity of patent laws between the U.S. and the foreign country, filing within 12 months of the date of foreign filing, and compliance with §102 (no patenting anywhere more than a year before the U.S. filing, and no U.S. publication or sale in the same time frame) – no special form for claiming foreign priority, but the foreign oath or declaration should identify the same invention as in the U.S. patent application
- Petition to make special: In certain circumstances, an application may receive expedited review and issuance, and an accordingly longer patent term – usual criteria (37 CFR §1.102): (a) an inventor is over 65; (b) an inventor's health might may soon him unavailable to assist in prosecution; (c) the invention is related to the environment, energy conservation, recombinant DNA safety, radioactivity, terrorism, or HIV/AIDS and cancer vaccination; (d) commercial manufacturing is awaiting issuance of the patent; actual infringement is occurring; or (e) the applicant has conducted a thorough novelty search – disadvantages of petition to make special: raises costs, potential for invalidation – it's recommended to hand-deliver these documents directly to the group responsible for deciding whether to grant it
- Filing procedure: The patent application should be submitted with a cover sheet, which identifies the submitted documents, the title of the invention, the names of the inventors, and the claim for small-entity status – the fee should be submitted with a Fee Transmittal Form, which includes some formulae for calculating the

total fee – the fee can be paid by referencing a deposit account with the USPTO or by check (credit cards not accepted); the fee transmittal form may also authorize the USPTO to charge this account for any additional fees (good practice, since nonpayment can cause abandonment) – if the applicant desires notice of filing, a self-addressed stamped postcard can be submitted with the application, and will be returned with the application serial number and date of filing, which serves as *prima facie* evidence of receipt by USPTO – the application can be submitted by hand delivery or mail service; submission by USPS Express Mail will cause the application to receive a filing date as of its mailing, if submitted with a certificate of express mailing (37 CFR §1.10(a)-(b))

Chapter Two(A): Electronic Patent Application Filing

- Overview: The Electronic Filing System (EFS) accepts utility applications, but not design, plant, or reissue applications – the system has several advantages (always available; immediate checking of application completeness; reduced costs and turnaround time), but is early in development and can be error-prone, and much of the detail about its current state is in flux – submitted documents must be formatted according to a particular XML schema, and the USPTO released a patent application authoring package called EFS-ABX to ease the transition – the USPTO also offers software called USPTO Direct (PAIR) for generating digital certificates, and ABXPDF Writer for PDF conversion, and ePAVE for formatting and submitting applications – some people have had more luck with PCT-based authoring tools (PCT-EASY, PCT-SAFE, PatXML), but these may not format correctly
- Software overview: The USPTO controls user access to EFS by distribution of "high-level security certificates," which requires a USPTO Customer Number (one per organization/law firm) and the generation of a digital certificate (one per individual) – in response to this request, the USPTO sends the applicant a Reference Number (by email) and an Authorization Code (by regular mail) that are used with USPTO Direct to generate a certificate – because this process involves a substantial delay, applicants may obtain a "low-level security certificate" by having only a verifiable email address, and may submit using ePAVE, but can't do anything with this method other than submit an application – once the applicant has a certificate, he can download EFS-ABX for writing the application; this software saves the completed application as a Word DOC, an XML file, and a PDF – this software relies on a plug-in called ABXPDF Writer (essentially a freeware version of Acrobat Distiller) – when the application is ready for submission, the applicant can use ePAVE to package together the XML and PDF files and to submit them to the USPTO – alternatively, the application can be written using the XPORT and PASAT software packages designed for PCT electronic filing, and the output files can be loaded into ePAVE for packaging and submission
- EFS-ABX: This software package is really just a Word template (ABX.dot) with some macro features built in – the template contains sections for the title, description, claims, abstract, etc.; formatting options are limited (bold, italics, superscript, underline; paragraph indentation; table formatting) – alternatively,

parts of another Word document can be imported into these sections in the template, but the imported text should have no special formatting; the EFS-ABX template includes a toolbar with formatting options that includes a Normalize function to scrub formatting for imported text – the toolbar also allows the insertion of drawings (converted to TIFFs and embedded in the document), and the creation of a Definition List, which creates a two-column table matching terms with definitions – when the application is complete, it is saved as described above, and the PDF should be reviewed for completeness and accuracy

- PASAT and XPORT: PASAT is out of date and being deprecated, but is still in wide use – this application requires sections of text to be pasted into different textboxes in the software application, and writes output as two proprietary files (.s4w an d.s4t) – these files can be imported in ePAVE, but can't be reviewed for accuracy (which ePAVE requires before submission) – also, imported images must be of a very specific format (300-dpi black-and-white TIFFs), or they won't import properly – because of these shortcomings, this software package is not recommended
- Electronic submission of patent applications: All drawings must be submitted as 300dpi black-and-white TIFFs no larger than 7.5"x10" (the EFS-ABX software accepts images in any format and automatically converts them to valid TIFFs upon saving the application) – ePAVE can include a declaration and power-of-attorney, executed with electronic signatures, as part of the electronically-submitted patent application; also, biosequence data can be submitted as an ASCII text file – when the application is complete and validated, it can be submitted to the USPTO via ePAVE; the USPTO sends data to ePAVE that constitutes an acknowledged mailing receipt, complete with patent application serial number, but the filing date will not be officially awarded until a USPTO officer has reviewed the application and accepted it as a complete submission
- Submission of other documents: ePAVE can be used to submit Information Disclosure Statements; this process is straightforward, but some examiners may not monitor the e-IDS service, so it is helpful to fax a single-page Notice of Filing Electronic IDS to the examiner – assignment documents can be scanned and submitted to ePAVE, but are more often faxed directly to the Assignment Division, which is accustomed to receiving faxes and can process them quickly
- Electronic signatures: The USPTO accepts digitized signatures to substitute for hand-signatures on patent documents – these signatures are usually written in this manner: "/*David J. Stein*/ David J. Stein, Reg. No. 47965"

Chapter Three: Working With the Inventor

- Inventorship defined: Inventors must be correctly named for patent validity, but is often difficult – circular definition of inventorship cited in 35 USC §102(f): "A person shall be entitled to a patent unless he himself did not invent the subject matter sought to be patented" – inventorship attaches to conception of the invention, not the perfection of embodiment details; "to claim inventorship is to claim at least some role in the final conception of the invention" (*Mueller Brass Co. v. Reading Indus., Inc.* (1972))) – "conception" is defined as "the formation in the mind of a definite and permanent idea of the complete operative invention and

method of obtaining it"; must also contain "conceptual specificity," i.e., in sufficient detail to constitute enablement (*Bd. Of Educ. v. Am. Bioscience, Inc.* (2003)) – this conception must also include utility, not merely a method of making a novel material of unknown use – however, enablement need not be perfect, but only sufficient to create a reasonable hope of success (note: the chemical arts are considered unpredictable, so there is no "reasonable hope of success" until it's actually tested)

- Joint inventorship: 35 USC §116: "when an invention is made by two or more persons jointly, they shall apply for a patent jointly" – each inventor must have contributed to at least one claim, or at the very least must have suggested an element comprising a limitation in a claim – contributing one alternative means imported into a means-plus-function element may be sufficient for inventorship, or it may be a non-inventive simple reduction to practice (*Ethicon, Inc. v. U.S. Surgical Corp.* (1998)) – the inventors cannot be "completely ignorant of what each has done until after their individual independent efforts" – joint inventors need not work in the same place or at the same time, but must still have collaborated in some sense (*Kimberly-Clark Corp. v. Procter & Gamble Distrib. Co.* (1992)) – contribution must be to a material portion of the invention; inventorship is not conferred by suggesting an obvious idea, serving as a laboratory technician or consultant, or explaining how the invention works
- Determining inventorship: First, define the invention and how it differs over the prior art – next, the contribution of each inventor should be assessed – the standard of inventorship must be explained to the inventors, who may mistakenly equate it with the academic authorship standard – the practitioner should ask about inventorship of anyone who contributed to the idea, including technicians, engineers who created prototypes or drawings, etc. – in general, it's better to include an inventor than exclude him; but close calls can be submitted to the USPTO for consideration via an Invention Disclosure Statement – if an inventor's contribution is negated during prosecution (e.g., a discovery of prior art encompassing his contribution), he should be removed as an inventor – if an error in inventorship (either misjoinder or nonjoinder) is discovered after patent issuance, the inventor can usually correct the defect by paying a fee and showing lack of deceptive intent (35 USC §116) – fortunately, the burden of disproving inventorship in litigation is "clear and convincing evidence" (*Eli Lilly & Co. v. Aradigm Corp.* (2004))
- Conducting the interview: The goal of the meeting should be to decide on a protection strategy, and to obtain a disclosure sufficiently enabling to conduct a novelty search; the details can be filled in as needed during drafting – the inventor should submit all relevant material to the practitioner for consideration before the interview – during the meeting, first let the inventor describe the invention; keep copies of drawings, and take photographs of prototypes – ask the inventor to differentiate the invention from the prior art (keep notes of cited relevant art) – then, tell the inventor about other types of protection (design patents, copyright, semiconductor chip protection, trademark/servicemark, trade dress, trade secret) and the details of each; also, discuss reasons for filing a patent application promptly, later, or not at all – if patenting is appropriate, walk through the

invention and try to find equivalents for each element (material types, fastening mechanisms, combining/dividing/omitting parts, etc.) – helpful practice: ask the inventor to give a unique name for each element – finally, go through the factors that might impact patentability (public disclosures, offers for sale or licensing, continuing work, federal funds involvement, etc.); it may be helpful to have a checklist on hand to itemize all such topics – conclude the meeting by agreeing to next steps – important: sign and date all documents received

- Drafting and executing the application: After drafting the application, it should be reviewed with the inventor prior to filing, preferably along with a draft IDS – this can be coupled with execution of formal papers (declaration, etc.)

Chapter Four: The Novelty Search

- Overview: A novelty search is a report of the prior art surrounding and overlapping an invention, and is intended to demonstrate whether an invention is novel and nonobvious – this differs from a "patentability search," which is much more thorough, and is conducted by a litigant or potential licensee – a novelty search usually contains a list of parameters for the search requested by the practitioner, a list of references found and considered by the searcher, a detailed review of the references, and a conclusion about novelty – advantages of a novelty search: economic advantage of deciding patentability and freedom to operate before spending money on patent preparation, and even on initial commercial efforts; higher-quality application (circumvents the prior art, use of industry-standard terminology, and written with an eye toward the level of skill in the art); avoidance of breadth narrowing due to amendments creating *Festo* estoppel; preparation of foreign filing strategy – on the other hand, a search might not be desired if the budget is tight or the filing time frame is short (though the search can be performed in parallel, or less desirably after filing)
- Procedure for ordering a search: Most practitioners do not conduct their own searches, but rely on a search agent – selection of the agent is important, because an inaccurate search is worse than no search – the search request should fully describe the invention (drawings, photos, etc.) and its advantages – the search request should then specify the search budget (usually about $1,500), the sources to be searched (USPTO records, foreign patent databases, technical literature), and the expected deadline for the search – the searcher might have to consult with a USPTO examiner in the art, or conduct a manual search the physical files for a patent class at the USPTO; both are common and effective strategies – finally, the searcher should be encouraged to consult with the practitioner during the search about other search areas and strategies
- Novelty search report to client: The results should be summarized with an emphasis on search scope, a boilerplate definition of novelty and nonobviousness – the report should *not* include patentability opinions, especially in the negative, since this is potentially discoverable – the client should be carefully advised that "perfect" searches are impossible and economically wasteful, since relevant prior art may be misclassified, opaquely entitled, or in a foreign language or obscure journal – thus, stress that the search is not a guarantee

Chapter Five: Drawings

- Overview: Drawings are often necessary to understand the invention and enable the disclosure; in many electrical and mechanical cases, the drawings are the clearest representation of the invention – may bear critically on the scope and interpretation of the invention – 35 USC §113: drawings are required "where necessary to understand the invention sought to be patented"; if drawings are missing but deemed necessary, the application may not even be given a filing date (presumed necessary for machines and circuits, and not necessary for compositions of matter and processes) – in borderline cases, the examiner might accept the application for filing but order additional drawings to be filed within two months – however, later-filed drawings cannot remedy an inadequacy of the application as filed, and cannot support a broader claim scope that is not supported by the specification as filed
- Formal vs. informal drawings: The USPTO provides and enforces many detailed rules for patent drawing conventions – "formal" drawings comply with all of these requirements, but are pretty expensive – one strategy is to file rough sketches, known as "informal" drawings, and to order formal drawings only if the patent is allowed – informal drawings must at least be readable, reproducible, and permanent (can't be in pencil, but can be a photocopy of a pencil sketch)
- Contents of drawings: The essential purpose of the drawings is to supplement and enable the specification – the drawings must show every relevant and novel feature of the invention (USPTO position: "every noun" in the claims should be depicted in the drawings; it's good practice to match the claim elements to drawn features before submitting the application) – for improvement inventions, it is helpful to submit a drawing of the prior art, and then a drawing of the improved device (note: clearly label the former as "Prior Art")
- Kinds of drawings: Perspective view (i.e., isometric) is a very natural way to draw an apparatus, and the USPTO often selects it for the first page of the issued patent; the viewing angle should be chosen to convey the most information – top/bottom ("plan view") and side ("elevation view") perspectives are helpful for dimensionally complex inventions; usually one aspect is most informative, and is presented first – sectional views reveal the inner construction and operation of the invention (either via a full sectional view, or a partial cut that also shows the outer surface); if the sectional plane is not apparent, it should be shown by a cutting plane line – exploded views show how the parts of an invention fit into an assembled whole – flowcharts can illustrate the steps in a conventional process – graphs and charts can depict experimental data and results to prove utility or improvement – schematics can be used to illustrate the steps of a chemical process, or the layout of a circuit – chemical structure drawings describe the physical structure of a complex organic composition – "invention in use" drawings show the invention interfacing with environmental or prior-art objects, or with people – finally, drawings can contain a sequence list for DNA or protein, or a computer program listing
- Preparing the drawings: Drawings are almost always prepared by patent illustrators, in light of the very detailed drafting rules promulgated by the USPTO – the practitioner specifies the needed drawings and the budget for preparing them

– the practitioner should send the illustrator a description of the invention, and any sketched drawings or photographs; it's particularly helpful to send a prototype – if the drawings must reflect the type of material, this should be indicated on the sketches – though drawings are expensive, it's better to err on the side of too many, since this will not prejudice the patent validity or scope – the practitioner might also send the illustrator a sample "description of the drawings" to coordinate figure numbers and element labels

- Overview of formal requirements of drawings: 37 CFR §1.84 sets forth many technical requirements for acceptability of patent drawings – however, these standards are less rigorously enforced than in previous years, and the threshold of acceptability reduced to "suitable for reproduction"; the requirements should still be substantially met for guaranteed acceptance – if rejected, the draftsman will indicate the deficiencies and allow the applicant to correct them
- Formal requirements in detail: All drawings must be submitted in ink or equivalent on A4 or 8½"x11" paper, with 2½cm top/right, 1½cm left, and 1cm bottom margins, and should be labeled with the title of the invention, inventors' names, invention serial number, and name and telephone number of an applicant contact – the components must be scaled to accurate proportions, and the drawing should be large enough to retain image features when scaled down 66% – regular portrait orientation is preferred, but landscape orientation is acceptable – drawings should be in an illustrative style, not an engineering schematic or blueprint – the drawings should be numbered in order of appearance – the reference numbers of elements in the drawings should be sequentially numbered, but like parts shown on multiple drawings must always be referenced by the same number (and the numbering for the elements should start after the numbering for the drawings; if submitting 19 drawings, the first element reference should be number 20) – any style of lettering is fine as long as legibility is retained – lines should be thick and well-defined; cross-hatching and shading should retain visibility when reduced – also, lines should appear differently depending on their purpose (object lines, cutting plane lines, projection lines, hidden lines, lead lines, and center lines all have specific styles and rules) – shading should progress from the upper-left at a 45^{o} angle, and should bend to reflect the size, shape, and characteristics of the surface (mirroring, screw-threading, rough surface, etc.) – cross-hatching can be used to represent fabric (e.g., wood grain) – many technical symbols can be used to represent fluid power dynamics, circuit design and current flow, process flow, pipe fittings, etc. (see *U 32.2 – 1970 Graphic Symbols for Electrical and Electronics Diagrams*)
- Special forms of illustrations: Photographs qualify as informal drawings, but are very rarely accepted as formal drawings (only if photography is the only practical medium for the invention, e.g., electrophoresis gel results) – colored drawings and colored photographs are even more often rejected; the applicant may file a special petition (37 CFR §1.84), and if granted, the specification must read verbatim: "The file of this patent contains at least one drawing executed in color. Copies of this patent with color drawing(s) will be provided by the Patent and Trademark Office upon request and payment of the necessary fee." – computer program

listings: only valid exhibits if containing no more than 300 lines of code @ 72 characters per line

Chapter Six: Preparing the Claims

- Purpose: The claims are the most important part of the patent, since they define the invention in the novel and nonobvious context in which the patent is enforceable – the claims serve as the template for the rest of the patent, and are the principal medium and topic of communication with the USPTO
- Basic principles of claim drafting: Each claim must have a specific meaning and purpose, and should reflect how the invention will be used in practice – claim drafting begins with developing an understanding of the invention and its position against the prior art; the size of the gap between them determines claim scope; broader claims capture more competitors, but are more likely to be considered obvious – many practitioners start the drafting process with the claims, since the rest of the application can be written to support the claims; in fact, the claims can be used as an outline of the specification – also, drafting the claims first facilitates consistent terminology in the specification – the claims also determine the drawings to be submitted
- Basic requirements for claims: The specification must conclude with at least one claim, and the claims must begin on a separate page of the specification, beginning with a phrase like "we claim" or "what is claimed is" – 35 USC §112 requires claims that "particularly point out and distinctly claim the subject matter which the applicant regards as his invention"; the CAFC has imposed an enablement requirement ("whether those of ordinary skill in the art would understand the scope of the claim read in light of the rest of the specification" (*Union Pac. Res. Co. v. Chesapeake Energy Corp.* (2001)) – the claims cannot reference the drawing or specification fail to "particularly point out and distinctly claim" anything, unless that's the only way to claim them (e.g., concentrations of several elements in composition shown by phase diagram: "with said component content restricted to amounts beneath h the curve in the accompanying diagram" (*In re Tanczyn* (1953))) – the claims must include every essential element from the invention, but need not each how it works – 35 USC §101 sets forth five elements of each claim: must claim the invention as a statutory class; must be useful; must be new; must describe an invention created by the named inventors; and must not overlap with any other patent issued for this invention, including those filed by the same inventors
- Restriction requirements: Claiming more than one invention in a patent application prompts the examiner to issue a restriction requirement, compelling the applicant to designate one of the several inventions for prosecution in this application; the other inventions can be pursued in separate divisional applications, but this escalates the total prosecution cost – however, the definition of "independent and distinct inventions" is unclear and changing – MPEP §801 recommends separation if (a) the claims are directed toward different statutory classes; (b) more than one claim constitutes "the broadest," and they overlap in scope; (c) the invention contains multiple, separately patentable aspects; or (d) a novel composition of matter genus involves a large number of distinct species

- Claim components and formatting: Every claim must be written as a single sentence, ending in a period – the claim is written as (and in the order of) a preamble, a transition, a body listing the elements, and (optionally) a whereby functional clause – e.g., "a wagon comprising a platform, two axles, and wheels" – claim elements should be separated with commas or semicolons – claims with many elements should include a colon after the transitional clause – subparagraph style is preferred; long claims with heavily interrelating elements can preface the elements "1.", "2.", etc., which makes back-references easier (though this is redundant and unnecessary in most cases) – claim elements can be correlated with drawing elements, though this is only for clarity and has no impact on claim breadth – example of claim incorporating these suggestions:

    An apparatus comprising:
        A first element (4);
        A second element (6) on top of the first element, comprising:
            A first subelement (8), and
            A second subelement (10); and
        A third element (12) connecting said first and second subelements,
    whereby the elements necessarily achieve a particular result.
- Preamble: The preamble can be used to summarize the type of invention, suggest its purpose or goal, identify its relationship with the prior art, and/or introduce objects with which the invention interacts (but that are not part of the invention) – the preambles help differentiate the aspect of the invention sought to be claimed (some claims may designate an apparatus, others the method of using the apparatus) – a long preamble might need to restate the type of invention ("an apparatus for working with an article, the apparatus comprising…")
- Preamble as limitation: Much has been written about whether the preamble limits the claim – e.g., is a claim for an "optical wave guide" anticipated by the same design for a different purpose? (*Bell communications Research, Inc. v. Vitalink Communications Corp.* (1995)) – the preamble is limiting if it must be considered to give meaning to the claim (if it "breathes life and meaning into the claim" (MPEP §2111.02, and *Poly-Am., LP v. GSE Line & Tech., Inc.* (2004)), if the preamble creates antecedent basis for other elements, if the preamble is clearly intended to distinguish the claim from the prior art, or if the claim is a Jepson claim – the preamble does not limit the claim if it merely describes the purpose or advantages of the invention, if it describes features not imparted by the claim, or if the claim body completely defines the invention on its own (*Marston v. J.C. Penney* (1965): claim to a "buoyant, flexible filler pad" could be extended to cover non-buoyant objects) – Jepson claim preambles are always claim limitations – in general, it's good practice to be clear: if intended as a limitation, the preamble clause should be repeated in the claim; if not, it should be deleted
- Transitional clause: Claims must include a transitional term to separate the preamble from the claim body – the most common transitional phrases are "consisting of" and "comprising"; each term affects how the claim is interpreted – "comprising" (sometimes termed "which comprises," "including," "containing," or "characterized by") is an "open" transitional term, indicating that all of the elements are essential but others may be added – "consisting of" ("constituting")

is a "closed" transitional term, indicating that the invention is defined as only the following elements (though compositions "consisting of" some ingredients also extend to the presence of trace, nonfunctional amounts of other ingredients) – intermediate interpretation: "consisting essentially of"; this is a "partially closed" transitional term often used for compositions, indicating that other ingredients may be present so long as they do not affect the properties of the invention (*Ziegler v. Phillips Petroleum Co.* (1973)) – ambiguous clauses like "composed of" and "having" require reference to the specification to determine scope, and thus are disfavored – "step for" is discouraged because it may or may not be interpreted as "step of" under 35 USC §112 ¶6

- Claim body: The body of the claim recites the essential elements of the invention and describes how they cooperate – each component is defined by its name, purpose, features, and interaction with other elements – the invention may comprise a single element, but this is rare – together, the claim elements define the steps of a process, the components of an article or apparatus, or the ingredients of a composition of matter – each element is introduced in its own clause, beginning with "a" or "an" (unless plural or described functionally by "means" or "step") to suggest that this is the first time it's being mentioned – after its introduction, an element should be subsequently referenced as "the" or "said", and its name should be consistently used throughout the specification, claims, and drawings
- Naming elements: Each element should be given a unique descriptive name – the names might be specific ("a nail") or broad ("a fastening component" or "fastening means"), depending on the prior art, but cannot be completely generically ("thing") – ; the inventor can "serve as his own lexicographer" by defining new terms or ascribing a specific definition to a common term, but cannot name elements deceptively – where not defined, an element will be interpreted according to ordinary or technical dictionary definitions – if several components are identical but in different places/functions, they may be uniquely prefaced "first" and "second," or "left" and "right," etc.
- Functional claiming: Each element can be named and claimed according to its function (35 USC §112 ¶6); this can be triggered in several ways ("mechanism or", "element for") but is most clearly initiated as "means for" or "step for" followed by a gerund (later referenced as "the [gerund] means") – one good use of means-plus-function language is to claim a structural element that performs more than one function, listing each as a different means and function – this style alters the scope of the element; according to the CAFC, the element definitely covers all means suggested in the specification for satisfying the means and all equivalents thereof (this concept is in flux) – thus, it's helpful to recite as many means as possible in the specification ("a nut and bolt, a hook, adhesive, an epoxy, magnets, rivets, soldering, welding, surface tension, nailing") – alternatively, this same broad interpretation can be achieved by reciting a very general structural term, like "fastener" – means-plus-function interpretation becomes less certain if the claim also recites a structure for the element (e.g., "means for fastening, such as a nail"; see *Unidynamics Corp. v. Automatic Prods. Int'l Ltd.* (1998)) – the key

factor is whether the claim describes what the element does or how it does it (*Masco Corp. v. U.S.* (2002))

- Functional language: Separately from reciting an element as a functional means, a claim can end with functional language ("whereby the articles are retained in the container during shaking") – this clause should describe a result that necessarily flows from the recited structure and interaction ("reacting A and B under condition C, whereby product D is formed") – it should not be used to add limitations to particular elements, which is unclear and imprecise, nor to describe a feature/goal/limitation of the invention not flowing from the disclosed structure ("a container for articles, whereby the articles are retained as they are shaken")
- Grouping and ordering of elements: The elements should be ordered in the claim in any way that makes them easy to understand – each element beyond the first should be recited with relationship to previously mentioned elements; thus, the first element should be an easy-to-describe element to which other elements can easily be related – sometimes an element can't be related until a connective element is later introduced ("an A, a B, and a C connecting A and B") – the elements may be grouped by type of cooperation: structural (start with the base, then the elements physically connected to the base, and work outward; or specify the power source, then electrical elements working outward), functional (relate elements by their operative interactions), chronological (describe a process as a step flowchart; sometimes the order may not matter; this should be affirmatively stated in the claim)
- Cooperation of elements: The elements in a claim cannot be a set of unrelated components, "like so many parts lying in a box" (*Ex parte Adams & Ferrari* (1973)) – common analogy: do the parts operate more like a football team or a track team? – unrelated sets used to be commonly rejected as an "aggregation," but a *per se* rejection on this basis has been discouraged (*Ex parte Nolden* (1965)) – today, the elements do not need direct cooperation, or even to function simultaneously, so long as they achieve a common inventive purpose – common test of interaction: diagram parts of an apparatus as a unit, or the steps of a process as a flowchart, and determine if any element is disconnected – common terms for relating elements: proximate, adjacent to, contiguous, adjoining, overlapping, near, connected to, alloyed with, engaging, fixed, adhered, pivotally/rotatably mounted, after, before, simultaneously, synchronously, asynchronously
- Grouping and enumeration of claims: A patent with one claim need not enumerate it – most patents have more than one claim, and the claims should be ordered from broadest to narrowest scope – claims of like species should be grouped together (first all apparatus claims, then all method claims) – when submitted, the claims should be consecutively numbered starting with 1, and should not be renumbered during prosecution (new claims are just appended and given the next highest number); when the patent issues, all of the allowed claims will be reordered and renumbered – each dependent claim should follow its parent claim as closely as possible
- Independent claim: An independent claim stands on its own, and does not reference any other claim – it can be broad (claiming only the essential elements

in generic terms or means-plus-function style) or narrow (specifying many components in specific detail to describe the preferred embodiment)

- Dependent claim: A dependent claim references a lower-numbered "parent" claim ("the apparatus of claim 1"), a transitional clause ("further comprising", "in which", "wherein"), and a claim body that adds new elements, further limits elements in the parent claim, or both – of course, new elements must be related to existing elements – a dependent claim implicitly imports all of the limitations and details of the parent; a dependent claim cannot delete any element or limitation of its parent claim (except for a narrower Markush group claim; see below)
- Multiple dependent claim: A claim can reference several parent claims in the alternative (correct: "the apparatus of claim 1 or 2, further comprising…") – multiple dependent claims must explicitly enumerate each of the parent claims (incorrect: "claims 1-3" or "any preceding claim"), must be in the alternative (incorrect: "apparatus of claims 1 and 2"), and must be only one set for one reason (incorrect: "the apparatus of claim 1 or 2, made by the method of claim 3 or 4", though deleting "or 4" makes this permissible) – finally, a multiple dependent claim cannot specify another multiple dependent claim as a parent claim
- Jepson claim: This claim style is used to claim an improvement of a known invention – the claim includes a preamble claiming "an improvement of" and specifying the known invention, a transitional clause ("wherein the improvement comprises"), and a description of the changed elements – this claim style is fully allowable by the USPTO, and is common in foreign applications – however, it is usually avoided in current practice for several reasons – first, the preamble is always construed to state admitted prior art that may limit or defeat patentability – also, the novelty is more narrowly construed as the improved elements, not as the overall novel combination – finally, it may be hard to draft this claim without secure knowledge of the prior art, which is rarely known at the time of drafting
- Markush group: Where an element can be selected from a series of alternatives, it may be clumsy to state the alternatives, means-plus-function style may be undesirable, and a generic term may be unavailable or overbroad – instead, the options can be listed as a set of alternatives: "material selected from the group consisting of A, B, and C" – common uses: alternative ingredients in a composition, alternative mechanical elements in an apparatus, or alternative steps in a method ("wherein the protein degrading step is heating, shaking, or enzymatically restricting") – requirements: the transition clause must be closed ("consisting of") if stated, but the formal language can be shortened ("wherein the element/limitation is A, B, or C") – "and"ing the group members results in protection of only one member of the group; if combinations are to be covered, either include "and combinations thereof", or "at least one of A, B, or C" – all Markush elements must bear some common feature that forms the reason for their communal usefulness for this component: common physical or chemical characteristics, or common functional utility, not merely the ability of achieving the same result (though potentially different processes) – one Markush-group claim may depend on another Markush-group claim with some elements omitted, to serve as a narrower claim – Markush groups can be problematic: if any one element is within the prior art, it can anticipate or obviate the whole claim; the

claim can be salvaged by striking the element, so long as the other elements aren't equivalents of the stricken element

- Product-by-process claim: This claim type claims a product by specifying the process used to create it ("a composition prepared by the steps of…" or "by the process of claim 1") – specific wording is required to trigger this interpretation; merely describing a product as having features imparted by a process ("etched", "interbonded by interdiction") does not result in a product-by-process claim – the product must be novel and nonobvious, though the process can be old and unpatentable – precedent is split as to whether the process is a claim limitation (such that the patent only covers products made with that process) or whether the process merely describes the product (such that the patent covers the product as made by any process) – these claims used to be allowable only for products with unknown characteristics, or those difficult to describe by the characteristics; but they are now allowable for any product (*Ex parte Hartmann* (1975))
- New use claim: A new use of a known process, machine, or composition of matter is patentable – precedent is split as to the patentability of old processes that use novel starting material or produce novel products – biotechnology processes are specially patentable in either case, even where the process is obvious
- Medical method claims: 35 USC §287(c) precludes enforcement of a patent against any medical practitioner for use of a method, unless the method involves a patented apparatus or composition of matter – thus, the method should be claimed to include the use of the patented apparatus or composition, especially if the object has no substantial noninfringing use – this will allow the patentee to avoid the enforcement estoppel impact of §287(c)
- Kit claim: Apparatuses are sometimes claimed as "kits," so that they can be sold in an unassembled but patented state – it should be written just like an apparatus claim, only the elements have no cooperative language
- Claim drafting strategy: The goal of patent prosecution is to obtain allowance of the broadest claims that do not encompass prior art – the claims should cover all suggested embodiments, and all relevant categories of patentable matter related to the invention – the most common tactic is to include a range of claims of varying scope, so that the patentee can initiate enforcement proceedings based on the narrowest claim that covers the accused infringer – this is also good practice because the degree of coverage by the relevant claim is directly related to the damages calculation (higher damages if the accused invention is "substantially identical" to the claimed invention) – if a question of patentability exists for a limitation, try drafting it as an independent, unlimited claim and a dependent claim adding the limitation
- Drafting the picture claim: This claim is simply a written description of the features of a specific embodiment of the invention – this can be claimed in varying scope: first, draft a claim mentioning all elements in detail for a narrow claim; then, eliminate all unnecessary limitations and elements for the broad claim; finally, add a few limitations and elements for an intermediate claim – added limitations can involve descriptions of subelements, materials or physical characteristics of an element, connective elements, or details of the interaction of

steps or elements – the narrowest claim is likely to be allowable (and quickly allowed), and the strongest offensive tool against a literal copier

- The broadest claim(s): This claim must come as close as possible to the prior art boundaries without overstepping them – this claim cites only the most essential elements, in the most general form, and renders the invention impossible to "design around" – the broadest claim is important because if it is allowed, all dependent claims are automatically allowable unless they raise 35 USC §112 issues (vagueness, etc.) – one good strategy is to feature a broad claim to a subelement of the invention that stands on its own for patentability (*Carl Zeiss Stiftung v. Renishaw PLC* (1991): a patent for a measuring probe included a claim to the mounting/positioning subelement; no circuitry involved at all)
- Writing the broadest claim: Except for Jepson claims, the preamble should state only the intended use of the invention, and the claim body should completely define the invention to prevent the preamble from becoming a limitation – the transitional clause should always use open language for the broadest claim – the claim body should be examined, on a per-word basis, for unnecessary elements and limitations that are not essential to the "inventive concept" – adjectives are especially ripe for removal; no need to specify an element as "rigid" if it can be flexible – nouns should be broadened as much as possible ("container" is more general than "receptacle") – means clauses can be used for any element where function is more important than structure, but the scope of means-plus-function elements is uncertain (*Valmont v. Indus., Inc. v. Reinke Mfg. Co.* (1993): this clause only reads on an accused device that (1) performs the identical function specified in the claims, and (2) "employs means identical to or the equivalent of the structures, material, or acts described in the patent specification") – thus, broader interpretation may flow from the use of a generic term clarified by a functional tail clause – after paring down the broadest claim, compare it against the prior art to make sure it is still novel and nonobvious; also, verify that the broadest claim covers all of the preferred embodiments and all of the drawings, including (especially) the commercial embodiment that the client will market as a product – it may be helpful to stretch out the language of the claim without introducing limitations, because examiners equate claim length with claim breadth, and may more quickly allow a less abbreviated claim; this can be done by adding structures that are nonessential and not necessarily helpful but inherently necessary – finally, it is always helpful to claim the environment of the invention, as this sets the stage for a royalty/damages determination; if the invention is a thermostat, to be used in a toaster oven, beginning the claim "In a toaster oven" will position the invention in the market of appliances, rather than cheaper appliance components
- Including multiple broad claims for broad protection: The broadest patents several broad claims directed toward different aspects of the same invention – such claims can be of different statutory classes: an apparatus, the process of making it, the process of using it, the article created by the apparatus, and the use of the article for a novel purpose – an important reason to include method claims is that these can ensnare competitors who use a patented method overseas to create an unpatented product, and then import the product; if method claims exist, the

overseas competitors can be found to infringe the U.S. method claims (35 USC §271(g)) – apparatus claims can be converted to method claims simply by specifying each structural as a step in a process; conversely, method claims can be converted to apparatus claims by specifying a machine comprising means for each step

- Writing the dependent claims: Dependent claims should not be overused, since in most cases their validity depends heavily on the validity of the parent claim – dependent claims serve a few purposes: (1) they can define the scope of the independent claim by additionally defining an element with a limitation that it *can* have, but need not (e.g., dependent claims to a method can demonstrate that the order of the steps is immaterial); (2) they can offer a range of patentable inventions to the examiner for speeding up allowance; (3) they can call out a preferred embodiment from a generic parent claim (e.g., if the parent claim recites a Markush group, a dependent claim can select the preferred option); (4) they can add specificity to a vague term in the independent claim (parent claim: "sufficiently long"; dependent claim: "at least five inches long"); (5) they specifically bring an embodiment within the scope of the patent, thereby foreclosing the argument that the embodiment was not claimed and thus dedicated to the public; (6) they increase the number of allowed claims in a patent, conveying an appearance of strength or breadth to non-practitioners – the same concepts apply to multiple dependent claims, which may lead to more organize prosecution (so that only one claim needs to be revised instead of several), but these can be sloppy and difficult of drafting them well; hence, multiple dependent claims should only be used to claim important secondary features
- Using means-plus-function language: Recognizing some ambiguity in §112 ¶6 interpretation, the USPTO issued some "Supplemental Examination Guidelines for Determining the Applicability of 35 USC §112 ¶6," proposing several tests of equivalency: (1) "whether the prior art performs the function specified in the claim in substantially the same way, and produces substantially the same result; (2) whether a person of ordinary skill in the art would have recognized the interchangeability of the element shown in the prior art for the corresponding element in the specification; (3) whether the prior art element is a structural equivalent of the corresponding element in the specification; (4) whether the structure, material, or acts disclosed in the specification represents an insubstantial change which adds nothing of significance to the prior art element" – however, these tests are difficult for examiners to apply, so they still just issue obviousness rejections based on prior art elements – in that case, the applicant bears the burden of proving non-equivalency; can focus on prior-art teachings of non-equivalency (narrowing the claim breadth), or Rule 132 affidavits (providing grounds for invaliding the claim) – thus, means-plus-function claims are a little risky – one way to reduce risk is to include an explicit definition of equivalents of a component in the specification – also, if means-plus-function interpretation is intended, the rules for such claiming should be well-respected; the CAFC has been withholding means-plus-function interpretation for claims that read "means of," or those that suggest a structure in the claim body – the "single means rule" should be respected to avoid a claim to literally any device that could accomplish

the stated purpose ("an apparatus for shaking articles, comprising: means for isolating the container during shaking"); if available, a generic structural term of the same breadth should be used in place of means-plus-function language ("fastener" is preferred to "means for fastening")

- Using functional language: An alternative to §112 ¶6 risks is the use functional language, including a whereby clause that describes the necessary result of previously defined structure (*In re Ludtke* (1971): a parachute patent allowably claimed ending, "said plurality of lines providing a radial separation between each of said panels upon deployment creating a region of high porosity between each of the said panels such that the critical velocity would be less than (x), whereby said parachute will sequentially open and thus gradually decelerate"; notice heavy use of gerunds to describe functional cooperation of elements) – the elements in this style are identified by generic nouns like "clamp," "cutters," "filter," etc., or by "___ mechanism" or "___ means" (which does not necessarily trigger §112 ¶6 interpretation)
- Using numeric limitations: Numeric limitations should be used when the measurement is critical to differentiate the prior art (e.g., unexpected results in certain conditions); the specification should make this clear – overly precise numbers should not be used; "60.00°C" has a narrower meaning and different impact on a jury than "60°C" – on the other hand, "about" can be used to increase claim scope: "a temperature of less than about 60°C" – this term is not indefinite (*BJ Servs. Co. v. Halliburton Energy Servs., Inc.* (2003)), but may create prosecution difficulties in light of the prior art, because it suggests that the numerical limitation is not a strong basis for distinguishing prior art – if used, it should be used consistently to modify all numerical ranges; inconsistency implies that the non-"about" ranges are more precise (*Jeneric/Pentron, Inc. v. Dillon Co.* (2000)) – less controversial is the term "substantially," which implies some proximity ("substantially below 60°C") – also, rather than using numeric limits at all, it may be helpful to use functional limits ("heating the ingredients sufficiently long that substantially all the ingredients are reacted"); the numeric figure can then be added in a dependent claim
- Using terms of degree: Open-ended qualifying terms will be acceptable where they have a reasonable degree of precision – "resilient," "flexible," "at least substantially hot," "sufficient to enhance," "substantially constant" have all been approved in some contexts; but "large," "small," "short," "high," and "long" are usually rejected – the latter adjectives can be made acceptably precise by clarifying in the specification just how long constitutes "long" in this claim, e.g., by relating it to some other element ("the second element longer than the first element") – a term that has two plausible interpretations might still be allowable, with the understanding that a court will have to clarify the ambiguity (*Hoffman-LaRoche, Inc. v. Burroughs Wellcome Co.* (1989)); but this is poor practice with indefinite protective scope
- Using trademarks and trade names: Trademarks and trade names are usually considered indefinite, because their meaning is fluidly defined by the trademark owner (*Ex parte Bolton* (1938): claim to "FORMICA" rejected as indefinite), and because a failure of the trademark (including a cessation of product sales) renders

the claim non-enabled – but where a composition is appropriately described in the specification, it can be referenced in the claims as an ingredient, so long as its meaning is clear (*Ex parte Stephens* (1945): "NAVILLITE" allowed to specify an ingredient in a claim where its composition was clearly defined in the specification)

- Negative limitations: It may occasionally be necessary to describe an element by negation, e.g., "a noble gas other than helium" – this language is not *per se* unacceptable, but must be judged on a case-by-case basis for overbreadth or indefiniteness (*Johns-Manville Corp. v. Guardian Indus. Corp.* (1983): a method claimed as "without using external attenuation" was held ambiguous, but "without using hot gas blast attenuation" was acceptable) – negative adjectives are more commonly accepted ("nonmagnetic," "colorless," and "noncircular" all approved) – where a positive limitation and an inverse negative limitation are both acceptable, the applicant has the right to choose (*In re Duva* (1967): "absent sufficient cyanide ions to prevent decomposition" was an acceptable choice, even though it could have been recited positively)
- Alternative language: Markush groups are very useful, but if any one of the alternative elements carries an embodiment into the prior art, then the whole claim is invalid – moreover, amending the claim to strike the offending element may narrow the claim as per *Festo* – if only a few species are present, it may be more sensible to claim each of them separately – ambiguity can support a rejection where alternatives are unreasonably conflated (*Ex parte Reid* (1879): "a spring or a weight" found improper use of alternative language), or where the genus/species relationship is unclear ("a holder, preferably a perforated box"), so the alternatives should have some (perhaps explicitly stated) commonality – while some leniency is being given to such alternatives (*In re Wolfrum* (1973)), alternatives so poorly claimed as to lack "unity of invention" are still rejected
- Terms to use carefully: Precedent is split as to whether "a" and "an" imply one or more items (*Crystal semiconductor Corp. v. Tritech Microlectronics Int'l, Inc.* (2001)) or exactly one item (*Reagents of the University of California v. Oncor Inc.* (1997)) – where plurality is acceptable, use phrases like "at least one" or "one or more" rather than simply "a" – similarly, "including" has been interpreted with a different meaning than "comprising" (*Toro Co. v. White Consol. Indus. Inc.* (1999)), so use "comprising" for appropriate breadth – where alternatives are specified, "or" creates some ambiguity: only one selection, or any combination of these elements, or multiple selections of one element? – this can be clarified with clauses like "only one of the following," "one or more of the following," "or any combination thereof," and "any number of each of the following"
- Antecedent basis: All claim elements must be first introduced as a claim element with "a" or "an" (or as a plurality), and then subsequently referenced as "the" or "said" – any reference to the claim element before its introduction is improper – subelements (e.g., different portions of an element) can be introduced along with the element, e.g., "a tube having proximal and distal ends"; however, obvious components don't need to be introduced at all (a tube is presumed to define a lumen, which does not need an introduction) – the environment and workpiece in/on which a device operates can be introduced inferentially in the preamble,

rather than as claim elements – holes and spaces should not be claimed as elements, but should be inferentially introduced ("a grommet having an eyelet") – also, the entire claim must have "clear support or antecedent basis in the specification" (37 CFR §1.75(d)); a rejection may issue if a claim element is not described in the specification, if a drawing is inconsistent with a claim, or if a claim element ambiguously describes one of several elements in the specification – one easy way to ensure antecedent basis is to include each claim verbatim in the detailed description portion of the specification – finally, the drawings must support the claims by showing every claimed element (37 CFR §1.83(a))

- Intentional ambiguity: Because infringement attempts are unpredictable, some ambiguity should be built into a few of the claims to make potential infringers more cautious – for this reason, it's better to have a patent of indefinite scope than one of broad but well-defined scope – means-plus-function language is ambiguous due to the precedent split, and can be made even more ambiguous by *possibly* invoking §112 ¶6 (recite "means of" instead of "means for," leave the "means" noun out of the clause, etc.); call the claims by different names in the specification; use open-ended ranges and subjective modifiers like "about" and "substantially"; use unclear transitional clauses like "having" and "composed of"
- Reducing claim count: Including too many claims can increase the cost of prosecution, and may draw an undue multiplicity rejection or restriction requirement – the examiner will usually have an idea of how many claims are "reasonable" for the disclosed invention, and will object if there are too many – also, rather than claiming several minor features in several dependent claims, the practitioner may combine them into one dependent claim suggesting many secondary features in the alternative: "A method according to claim 1 that has one or more of the following characteristics:" – similarly, an independent claim can consolidate several features: "An apparatus comprising: element 1, wherein element 1 has at least one of the following characteristics:…"
- Avoiding *Festo*: The Supreme Court ruling in *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.* (2002) created a basis for withholding the doctrine of equivalents from claims that had been amended to avoid the prior art – this ruling has disrupted the practice of patent drafting and prosecution, and tactics for avoiding this ruling are extensive – tactics include: claiming each species of a genus separately; heavier reliance on §112 ¶6 claiming, because "equivalency" under this section is different from the doctrine of equivalents (and presumably not affected by *Festo*); preparing claims more carefully during preparation, both to avoid the prior art and to avoid amendments for other reasons, like ambiguity; submitting multiple independent claims with overlapping scope, so that one or a few will issue without amendment
- Avoiding patent exhaustion and implied licenses: A patent licensed to a purchaser (or a product sold to him) has to allow him to make use of his purchase – thus, if a patent claims both an article and a method of using it, a court may interpret an express conveyance of one right to be worthless without an implied conveyance of the other right(s) – the doctrine of "patent exhaustion" is invoked to give a licensee or purchaser more rights under a patent than were expressly transferred – one way to avoid this doctrine is to claim the inventions in separate patents

- Claim-drafting errors: Inconsistent terminology should be avoided – an element can be more specifically named in a dependent claim to provide a narrower definition, but this can be clarified by describing it alternatively in the specification ("a bar, also referred to below as a lever") – indefiniteness can justify a rejection under 35 USC §112, if it would not be clear to "one of ordinary skill in the art"; while some leniency is due (*Georgia-Pacific Corp. v. United States Plywood Corp.* (1958)), an attempt to "corral the art by use of comprehensive indefinite terms" is not tolerated – indefiniteness can exist where a claim term ambiguously references antecedent elements (e.g., an invention with "rear wheels" and "front wheels" later recites a brake that engages "the wheels") – indefiniteness can also exist in the interaction of elements (e.g., one element "adapted to" another element) – functional language that states a desired result is rejected as overbroad (*In re Fuller*: "a woolen cloth having a tendency to wear rough rather than smooth" rejected as overbroad); it's better to state alternative materials that can achieve this purpose – laudatory statements (e.g., "a steam iron… whereby the iron presses clothes more effectively than heretofore") are surplusage that should not be included in a claim

Chapter Seven: Writing the Specification

- Overview: While the claims define the application, 35 USC §112 and 35 USC §101 set forth other requirements – the level of detail needed to satisfy each requirement varies by invention and component
- The utility requirement: 35 USC §101 requires the specification to demonstrate utility for the invention – the alleged utility needs to be specific ("anti-tumor substance" is too generic), substantial (can't be too tangential or distant from an actual utility; an assay for determining the presence of a material with no useful value isn't substantially useful), and credible – however, the degree of utility and threshold of proof are very low, and only one utility must be shown – these requirements are considered inherently demonstrated for most mechanical and electrical inventions (except for facially unworkable inventions, like perpetual motion machines) – the thresholds are higher for biotechnology, and the USPTO has issued guidelines for patentability of biotechnology inventions – this requirement can be safely satisfied by suggesting as many useful applications as possible
- The description requirement: §112 requires that the specification "shall contain a written description of the invention" – this requirement is intended to show what the inventor invented, and to teach the public how to use it – §112 ¶6 specifically requires the specification to set forth equivalent structures that might satisfy the claimed means, so the description requirement is not met if equivalents are omitted – recently, the CAFC and USPTO have raised the threshold of the description requirement (biotechnology inventions must specify the structure, name, formula, or chemical or physical properties) – in general, the level of detail required varies with the level of skill in the art, and with the predictability of the art – the description must prove that the inventor had possession of the invention, like actual reduction to practice or sufficiently detailed description of properties or implementation to prove possession – conversely, possession is disproven if

essential details are missing, if a composition is solely described as a method of making it without any description of its properties, or if the method of making is not sufficient for one of skill in the art – while this requirement is usually met when the application is filed, the requirement can be violated if claims are later added that are not supported by the specification (*In re Berkman* (1981): applicant filed a design patent for a storage cabinet, started selling it, and then (over a year later) filed a utility application for the cabinet; the latter patent was rejected because it couldn't claim priority back to the design application, which didn't satisfy the written description requirement of §112 – however, it's possible to satisfy the written description requirement with a sufficiently detailed drawing (*Vas-Cath Inc. v. Mahurkar* (1991))) –

- Satisfying the description requirement: One easy way to fulfill this requirement is to reproduce every claim in the specification, and to elaborate on each; if this is not originally done, the specification can later be amended to insert the claims originally filed (this doesn't constitute "new matter") – also, to allow for the opportunity to add claims at a later date that are supported by the specification (as filed), it's wise to file a broad and detailed specification that may allow broader claims to be added later
- The enablement requirement: §112 requires that the specification "enable any person skilled in the art to make and use the invention" – another view of this requirement is that the specification must be sufficient to reproduce the invention (*In re Gardner* (2001): application for antidepressant drug tested in rats did not disclose the kind of animal used to test for it, or the effective dosages of the drug); this test might fail if the starting material becomes unavailable to the general public – the "art" in question is whichever kind of technician would be used to implement the invention (*In re Naquin* (1968): a patent for a computer method of seismic prospecting must target an ordinary computer scientist, not an ordinary geologist) – also, the level of skill is estimated for the day of filing – the threshold for ease of implementation is anything less than "undue" experimentation; this level is related to both the average skill in the art and the predictability/consistency/reliability of the art – a great amount of routine effort does not equate to "undue experimentation" (*In re Wands* (1988)) – this requirement must be met for *all* of the claimed subject matter, not just part of it – in general, the threshold of enablement varies directly with the breadth of the claimed invention; there must be a reasonable correlation between the scope of enablement and the scope of the claims – this is particularly relevant for Markush groups: if the specification enables use of the invention for some species, and the others are similar enough to be similarly utilized, the invention is enabled (*U.S. v. Telectronics, Inc.* (1988)); but a claim to a genus of 150 poorly-understood species is not enabled by satisfying enablement for only nine species (*In re Vaeck* (1991)) – the examples used to demonstrate enablement can be either actual or prophetic (*Atlas Powder Co. v. E.I. Du Pont de Nemours & Co.* (1984)) – however, prophetic examples must clearly be denoted as such; one common stylistic mechanism is to describe actual examples in past test, and prophetic examples in present or future tense

- Limitations to the enablement requirement: Of course, the specification need not teach what those of ordinary skill in the art likely know – also, it does not have to explain how or why the invention works, only that it does work – also, this requirement applies only to claimed subject matter; if the application doesn't claim a method of mass-producing an article, then this need not be taught in order to claim the actual article (*Christianson v. Colt Indus. Operating Corp.* (1987))
- Satisfying the enablement requirement: In general, it's better to err on the side of caution and provide too much detail – a patent practitioner may be tempted to leave minutiae out of the application, but a reasonable amount should be included so that the enablement requirement is securely satisfied – it may help to have one of "ordinary skill in the art" read the application and decide whether or not the inventive concept is sufficiently taught
- The best mode requirement: §112 requires that the specification "set forth the best mode contemplated of carrying out the invention" – if the inventor knows of a better mode than that disclosed at the time of filing, and yet does not disclose it, the patent can later be invalidated; egregious cases can lead to awards of attorney's fees and disciplinary measures – thus, this requirement is both subjective and factual, based on the inventor's state of mind (*Chemcast Corp. v. Arco Indus. Corp.* (1990)) – all material details must be disclosed; if a specific compound is known to work best for a component, the patentee cannot suggest a general class that includes the specific compound (*Dale Elec., Inc. v. R.C.L. Elec., Inc.* (1973): inventor knew that using the materials of one manufacturer was optimal, but recommended using any material by any manufacturer) – this requirement specifies the best mode "known to" the inventor, not "invented by" him; even if it is not claimed, or is a trade secret or patentable method of another, it must be disclosed – as with the enablement requirement, the teaching must be clear, concise, and sufficient that one of ordinary skill in the art can practice the best mode without undue experimentation – if this teaching requires reference to unconventional or little-known knowledge or references, that knowledge must be explicitly included in the specification, since one of "ordinary skill" couldn't otherwise practice it – if the "best mode" requires the use of a compound that can't be produced without undue experimentation, the inventor may be required to submit a sample to a biomaterials depository (*Amgen, Inc. v. Chugai Pharm. Co.* (1991))
- Limitations to the best mode requirement: This requirement applies only to (a) claimed subject matter and (b) unclaimed elements that are necessary to operate the invention (a claimed golf ball outer shell design does not require suggestion of what material to use, if the material is not part of the design (*Spalding & Evenflo Cos. v. Acushnet Co.* (1989)); a patented process that begins with a routine starting material does not need to teach how to synthesize that starting material (*Eli Lilly & Co. v. Barr Labs, Inc.* (2000))) – the best mode only applies to the knowledge of the inventor as of the filing date; later discovery of better examples does not need to be added (and in fact cannot, since this would be "new matter") – the mode need not be the one that is commercially used by the patentee, who may continue refine the invention for commercial use after filing (*Atlas Powder Co. v. E.I. Du Pont de Nemours & Co.* (1984)) – the applicant is not required to identify

which mode is the best, so long as it is disclosed (perhaps as one of several alternatives – however, this cannot rise to the level of intentional concealment, such that undue experimentation is required to identify the best mode (*Loral Corp. v. B.F. Goodrich Co.* (1990)), or where the best mode is briefly mentioned but other modes are described in exacting detail (*Spectra-Physics, Inc. v. Coherent, Inc.* (1987))

- Satisfying the best mode requirement: One way of determining the "best mode" is to ask the inventor (near the date of filing) which of several modes he would use in practice; as long as this question is answered thoughtfully and truthfully, and is used in the application, the "best mode" requirement has been satisfied – however, safe practice involves disclosing more rather than less – if two modes are known, and each has advantages over the other, both should be disclosed – also, if a particular method is likely to be used commercially by the patentee, it should be disclosed, even if a better mode is known – if a material is trademarked, the applicant may specify its use by name; but specific properties and manufacturer should be disclosed in sufficient detail to define the composition of the trademarked material, so that it doesn't shift over time – also, all knowledge that might not be within the skill set of one of "ordinary skill" should be set forth in the specification, even if well-known by experts (*Thyssen Plastik Anger KG v. Induplas, Inc.* (1978)) – while identifying one mode as "the best" isn't required, it's good practice to do so anyway – because this requirement is unavoidable, it often forces the inventor to choose between patenting a process and retaining the best mode as a trade secret; such proprietary interests are not a defense to an invalidating failure to satisfy the best mode requirement (*White Consol. Indus., Inc. v. Vega Servo-Control, Inc.* (1983))
- Writing the specification: The specification serves two purposes: it supports the claims to allow patentability, and it serves as a "sales" document to demonstrate the value of the invention to a judge, jury, or potential business partner – thus, the application should not only teach the invention to one of ordinary skill in the art, but should describe its merits in ordinary language ("a new high-surface-area catalyst that allows polymer resins to be made 10% faster, and thus 10% cheaper") – some patent litigators establish a "theme" for the invention; this concept can be instilled into the specification as well – however, don't describe what "the invention" is, since this may change during prosecution; rather, stress the benefits of "one version of the invention" – a patent application contains the following parts: title, inventor list, cross-references to related inventions, statement regarding federally-sponsored research or development, reference to computer-readable media, background (field of invention and description of related art), summary, brief description of the views of the drawings, detailed description, claims, abstract, drawings, sequence listing
- Title: The title is placed at the top of the first page, and on the application data sheet – its length should be between two and seven words (PCT applications are limited to seven words, so drafting it this way originally avoids the need to change it later) – it can be adapted from the preamble of the broadest claim ("[An] apparatus for manufacturing ball bearings, [comprising…]") – the title should not be overly broad, since examiners may use it to define the scope of relevant prior

art ("apparatus for making spherical articles" can prompt the examiner to cite prior art for making golf balls, bowling balls, etc.) – also, the title may be used to clarify the claims (*Exxon Chemical Patents, inc. v. Lubrizol Corp.* (1985): patent entitled "lubricating oil compositions" limited to a composition rather than a "recipe") – in light of the sales purpose of the patent, the title can contain laudatory statements: "'improved' cellphone, 'high-efficiency' engine"

- Inventor list: The names of the inventors can actually be initially omitted, and added by amendment after filing – in the event of an inventorship dispute, this can allow the application to be filed before the dispute is resolved
- Cross-references: MPEP §201.11: The patent application must begin with a list of all patents on which the application depends for priority, as well as all related applications like divisionals – each reference should include the serial number and filing date, and may include the inventor list, title, and status of the application – this section should end with the following statements: "all of these applications and patents are incorporated herein by reference; but none of these references is admitted to be prior art with respect to the present invention by its mention in the background" – when this application issues (or is published?), the related applications lose secrecy status (37 CFR §1.14(a)) – also, the priority claim shortens the term of the child patent
- Government rights: Any federal sponsorship of the discovery, development, or refinement of the invention requires that ensuing patents reference a statement of such funding, and acknowledging the government's march-in rights
- Reference to CDs: The inclusion of material on a CD, usually a DNA or protein sequence listing, requires a statement that the contents are incorporated by reference – the CD-ROM must be finalized so that its contents cannot be changed after filing
- Background: Although the USPTO recommends that this section include a "field of the invention" and a "description of the related art," neither section should be included: the breadth of the stated field can impact the scope of the patent and/or relevant prior art, and the "description of the related art" may imply all discussed references are valid and relevant prior art – in fact, the background section should not admit anything as prior art unless this is unquestionable – instead, the background section should be a "sales pitch" for the invention, suggesting a desperate need for improvement in a technological art – the section can be used to characterize other references as "attempts to address these problems," but should be described in detail only by noting their continuing deficiencies (however, the applicant may not make "disparaging" comments about the prior art; this is especially true of the applicant's prior designs, because such statements could be considered product flaws in litigation over the prior designs) – the conclusion should summarize the need for the invention ("for the foregoing reasons, there is a need for a machine that can inexpensively produce perfectly spherical ball bearings")
- Brief summary: The brief summary should begin with a heading reading "Summary," not "Summary of the Invention" (again, because "the invention" that will be patented is unknown) – this section should begin: "The present invention is directed to a [statutory class] that meets these needs. The [class] comprises…"

– the contents of the summary describe the invention as a whole (which differentiates it from the abstract, which describes only the claimed subject matter) – some practitioners include the broadest claim verbatim in the summary; some "rewrite the broadest claim in English" in the summary; and some use the summary to describe the invention in very general terms – also, some practitioners prefer to write the summary in first person, which can be more appealing to lay readers – these options are really just personal preference, but in general, the specification should mention all novel and nonobvious elements and features, and the advantages of the invention over the prior art – the summary should close with a statement such as: "These and other features, aspects, and advantages of the present invention will become better understood with reference to the following description and claims"

- Brief description of the drawings: This section should be very short, and should enumerate the drawings and describe the perspective viewpoint of each – should have the form: "These and other features, aspects, and advantages of the present invention will become better understood with regard to the following description, appended claims, and accompanying drawings: Fig. 1 shows…; Fig. 2 shows…; and Fig.3 shows…" – each drawing should only refer to "one version of the invention," not to "the invention" (since the patentee is entitled to claim only one invention per patent)
- Description: This is the most technical part of the patent application, and the most difficult next to the claims – the specification must satisfy the requirements of §§101 and 112 – the claims and sketches of the drawings should already be on hand for coordination – each element should already have been uniquely named, and a list of terms of art to be used should be first prepared, along with the definition of each – also, it can be helpful to outline the detailed description, listing each element to be discussed in detail
- Description – overview: Rather than itemizing the items as in the claims, the invention should be described from a top-down hierarchial approach: first describe the total invention in each detail, then successively focus on each part down to the elements – this can be done for processes as well ("The process of making ethanol includes mixing the ingredients, separating the solids, and distilling the mixture. In the mixing step…") – complex inventions can have several layers of complexity, and should be described on a layer-by-layer basis – similarly, chemical compositions can state the overall structure, then define each constituent, then go into detail about specific side-groups that can be used for each constituent
- Description – elements: The elements should be described in sufficient detail to use, and maybe even reproduce, the invention – the level of detail is flexible, but it's safer to err on the side of too much detail – mechanical elements can be described in terms of function, size, shape, materials, configuration, orientation, cooperation with other elements, and substitutes – particularly in mechanical inventions, the names of elements should be carefully selected; the inventor can help with this – special focus is due for elements claimed functionally via §112 ¶6, with a list of equivalents provided; failure to suggest even one equivalent renders the invention non-enabled (*3, Inc. v. nVIDIA Corp.* (2001)) – however,

after stating a few equivalents, the practitioner can attempt to broaden this, e.g., "applicant intends to encompass any structure presently existing or developed in the future that performs the same function"

- Description – use and advantages: The description should describe how the inventor envisions the invention being used, and it is usually clearest to include this after (and separate from) the structural description – this allows the inventor to specify the inventions in light of the elements ("because the head and handle are coplanar, the article can be manufactured from one piece of sheet metal") – this section should refer back to the Background section and reiterate the advantages of the invention specified therein – however, this section should note that not every advantage is necessary for use of the invention; otherwise, a court may limit the patent, e.g., a substituted element is not an equivalent because it does not exhibit the advantage (*Vehicular Techs. Corp. v. Titan Wheel Int'l, Inc.* (2000)) – in fact, some practitioners omit any discussion of advantages in order to avoid this result
- Description – embodiments and examples: The invention can describe actual or prophetic examples – of course, at least one must be described to satisfy the "best mode" requirement; but others may be included to expand the patent scope to several embodiments (also helps expand the scope of terminology in a *Markman* hearing) – chemistry inventions particularly depend on working examples, since the art is less predictable – the level of detail should approximate that in a scientific article, and should include unfavorable data (failing to do so may constitute inequitable conduct) – each examine should begin with a statement of purpose ("this example shows how to manufacture A using B and C as starting materials") – the example may indicate a list of alternatives (in a more natural style than in the claim, e.g., "A is attached to B using a fastener such as a screw") – as noted, prophetic examples should clearly be indicated as such, and a common stylistic mechanism is to describe proven examples in past tense and prophetic examples in present or future tense
- Description – closing: The description should close with a statement like:

> Although the present invention has been described in considerable detail with reference to certain preferred versions thereof, other versions are possible. Therefore, the spirit and scope of the appended claims should not be limited to the description of the preferred versions contained therein. Any element in a claim that does not explicitly state "means for" performing a specified function, or "step for" performing a specified function, is not to be interpreted as a "means" or "step" clause as specified in 35 U.S.C. § 112, ¶ 6. In particular, the use of "step of" in the claims is not intended to invoke the provisions of 35 U.S.C. § 112, ¶ 6.

Also, the EPO may also require a statement incorporating the formal papers by reference:

> The reader's attention is directed to all papers and documents which are filed concurrently with his specification and which are open to public inspection with this specification, and the contents of all such papers and documents are incorporated herein by reference. All features disclosed in this specification (including any accompanying claims, abstract, and

drawings) may be replaced by alternative features serving the same, equivalent or similar purpose, unless expressly stated otherwise. Unless expressly stated otherwise, each feature disclosed is one example only of a generic series of equivalent or similar features.

- Claims: See above – the claims should begin on a new sheet
- Abstract: The abstract must be a single paragraph between 50 and 150 words, and should be directed to a description of the uses of the invention, not a comparison with the prior art – the abstract for a machine patent should describe its structure and operation; the abstract for an article patent should describe how it is made; the abstract for a chemical compound patent should identify its use and nature; the abstract for a method patent should describe the steps – formal legal language should be avoided (no "said" or "means") – the USPTO uses the abstract to triage the application to the correct practice group, and despite the CFR rule that the abstract cannot be used to limit the scope of the patent (37 CFR §1.72(b)), the CAFC has so used it on occasion (*Jeneric/Pentron, Inc. v. Dillon Co.* (2000))
- CD-ROM exhibits: Long sets of text or tabular data may be included on a CD-ROM submitted with the application (37 CFR §1.58) – DNA and protein sequences are often submitted in this way, and must meet stringent requirements for submitting sequence data
- Practice tips: Copyrights in patents: patents are not copyrighted documents, so ideas for specific language, claim strategies, etc. may be copied from other patents – however, specific elements (e.g., drawings) can be copyrighted, trademarked, mask worked, etc. – protected items should be clearly labeled with a copyright or mask work notice; the exact wording of the notice is set forth in 37 CFR §1.62(b)(6) – trademarks: as in the claims, trademarks can be specified so long as the subject matter is definite and unchanging, e.g., by referencing the technical name for a drug in addition to its marketing title – referencing a trademarked good only (perhaps ephemerally) available from one vendor may render the invention non-enabled – the MPEP contains a list of well-known (abandoned?) trademarks that can be used ("Velcro," "Freon," etc.) – because the value of using a trademark is not well-balanced against its dangers, it may be wise just to omit them – reference numbers: element identifiers used in the drawings must be consistent with thgose used in the specification – it's wise to begin numbering the elements past the highest-numbered drawing for clarity – also, many practitioners use only even reference numbers, in case other elements must be cited and enumerated – also, similar components (e.g., the legs of a table) can be labeled 1a, 1b, 1c, etc. – if different embodiments are shown, different series of numbers can be used to reference the elements (100, 102, 104, and 200, 202, 204); even better, shared elements should have the same subseries (102 and 202) – antecedent basis: as in claim style, the first time an element is reference in the specification should be prefaced "a" or "an," and all following times should be "the" or "said" – numeric limitations: as with the claims, specific numbers, especially with high precision, are to be avoided because they can be designed around; ranges should always be given, though a preferred embodiment or best mode can recite a value within the range – alternatively, words of approximation can be used ("about pH 5.0"), or the value can be specified in functional language

("heating to a temperature sufficient for completely degrading the protein") – incorporation by reference: the USPTO has different rules for this tactic depending on whether the incorporated material is "essential" – if so, only a U.S. patent or published patent application or a prior foreign patent application can be incorporated; copies of the reference must be submitted along with the application, and either the copies must be certified by the issuing body, or the submitter must submit an affidavit averring that the incorporated material is accurately reproduced – failure to do so is not fatal, but must be corrected prior to issuance – if the material is not "essential," then any reasonable publication can be incorporated – in either case, the specific portion of the reference to be incorporated must be cited – line numbering: most specifications include line numbers; alternatively, the paragraphs may be uniquely numbered, enclosed in square brackets [0001] and followed by four spaces

Chapter Eight: Information Disclosure Statements

- Overview: 37 CFR §1.56 requires attorneys to disclose relevant material that may be relevant to the patentability of an invention applied for patent – even if not required, submitting references to the USPTO for an examiner's consideration is good practice, since an allowance over known prior art strengthens the presumption of validity of the patent – the consequences for failing to disclose can be severe: unenforceability of the entire patent (*Kingsdown Med. Consultants, Ltd. v. Hollister* (1988)), award of attorney's fees, antitrust liability for false procurement of a patent (*Walker Process Equip., Inc. v. Food Mach. & Chem. Corp.*), and disciplinary measures against the attorney (35 USC §32)
- Disclosure threshold: Before 1992, the standard was that disclosure was required "where there is substantial likelihood that a reasonable examiner would consider it in deciding whether to allow the application" – in 1992, this threshold was lowered by the USPTO to resemble a "but-for" test: disclosure is required if (a) the material establishes or contributes to a *prima facie* case of unpatentability, or (b) the information is inconsistent with a position or argument brought before the USPTO regarding patentability – in this context, prima facie is interpreted in the following context: "giving each claim term its broadest reasonable construction consistent with the specification, and before any consideration is given to evidence which ay be submitted in an attempt to establish a contrary conclusion of patentability" (37 CFR §1.56) – however, the CAFC continues to apply the old standard of materiality, so this should be the threshold for general practice - in general, erring on the side of disclosure is preferable to the consequences of a Rule 56 violation; this principle is endorsed by the USPTO (MPEP §2004(10)), and submission does not constitute an admission of materiality (37 CFR §1.97(h)) – also, it's better to raise these issues during prosecution and deal with them accordingly, rather than letting them distract a trial jury – examples of erring on the side of disclosure: nonanalogous or nonprior art; evidence of the applicant's experimental/public/marketing uses of the invention; facts bearing on inventorship, priority, enablement; and references cited by an in-house patent searcher, by a U.S. or foreign examiner in prosecution of this or related

applications/patents; or references cited during litigation of related applications/patents

- When to disclose: If possible, the information disclosure statement should be filed with the application – to be considered timely, it must be filed before the later of (a) the first office action and (b) the expiration after three months of filing – untimely filed statements (after these deadlines) will be accepted if the practitioner files a statement explaining the delay and pays an extension fee (37 CFR §1.97) – after final action or allowance, the requirements and penalties further rise; and after the issue fee is paid, consideration of previously uncited references requires filing for reexamination – in any case, citing new information after the examiner has written a first office action is likely to frustrate him and complicate prosecution
- Contents of statement: The information disclosure statement is a list of patents, publications, and relevant information – if there are a large number of references, the practitioner should indicate which ones are most significant (MPEP §2004(13)) – the practitioner may specifically reference certain paragraphs or figures – English references should be provided without comment: rather than distinguishing the prior art and triggering a *Festo* limitation, it's better to wait and see if the examiner find the reference relevant – but non-English references should include an explanation of why the examiner may consider them relevant – of course, the statement should not refer to the references as prior art, but in fact should expressly disclaim any inference of prior art or relevance
- Submission of reference documents: 37 CFR §1.98: the IDS must be submitted with a copy or excerpt of each referenced document, except for U.S. patents, published U.S. patent applications, documents that are cumulative with others that have been submitted, and documents referenced by relation to another file – submitted foreign references must be submitted with a translation
- Electronic filing of invention disclosure statements: See chapter 2A for more info on submitting IDSs electronically

Chapter Nine: Design Patent Applications

- Overview: 35 USC §171 authorizes patents for any new, original, and ornamental designs embedded in an article of manufacture – the rules are substantively the same, but the patent application is much easier to draft (only one omnibus claim); in fact, a design patent is a simplified version of a utility patent, and it has the same sections (but with less content) – however, protection is very narrow, and covers only the whole appearance of the design and accompanying article, not any particular feature of the design – rather than protecting a useful invention, a design patent protects the visual impact of the design on an observer, and includes the shape and surface characteristics of the article in which the design is embedded – thus, the particular article on which the design is embedded is an essential limitation of the patent (MPEP §1502) – on this basis, a design patent application for a software icon will be rejected unless it is "for display screen of a programmed computer" or something similar – however, applicants can get creative in satisfying this requirement (*In re Hruby* (1967): design patent allowed for a shaped jet of water created by a fountain system)

- Ornamentality: Design patents replace utility with "ornamentality"; the pattern cannot be dictated by mechanical or functional considerations, and the design cannot be "primarily functional" (*Hygienic Specialties Co. v. H.G. Salzmann, Inc.* (1962)) – conversely, if the design is "primarily ornamental," it is patentable even if it also has some functional features (*In re Schilling* (1970)) – the issue is not resolved by an element-by-element analysis, but by looking at the design as a whole – design patentability is more likely if the applicant has chosen one of many arrangements that could satisfy a function (*Moore v. Stewart* (1985): a flute design was held to be patentable, even though it incorporated important functional elements like the length and hole placement of a typical flute, because alternative designs with functional equivalency were available) – however, the ornamentality cannot be offensive to any race, religion, sex, ethnicity, or nationality (MPEP §1504.01(d)) – also, the ornamentality cannot be "concealed during normal use," which is defined as visible at some moment between the assembly of the article and its destruction or disappearance – this is interpreted broadly ((*In re Webb* (1990)): an ornamental design on an hip implant was held patentable because it was visible when the product was shown in advertisements and trade shows)
- Relationship of design patents and other forms of intellectual property protection: An ornamental design can also be copyrighted or trademarked – in either case, the drawing submitted with the patent application should include a copyright or trademark notice, and a disclaimer should be included in the specification (see MPEP §1512 for exact wording)
- Design patent specification: The specification of a design patent should contain a title, a preamble, a description of the figure or figure, an optional description of the design, a claim, and a signed oath/declaration
- Design patent title: The title should describe the design and (more importantly) the article in which it is embedded, and should be in fairly plain language ("perfume bottle," "microwave oven," "automobile alarm"); this is encouraged because title does not narrow the scope of the patent – however, if the design can be embedded in a product used within a range of environments, the title can be appended "or the like" or "or similar article" to connote versatility ("door for cabinets, houses, or the like" is acceptable, but "door or the like" is not (MPEP §1501.01))
- Design patent description: The description of a design patent primarily describes each of the figures, in the same way as for utility patents (describe the point of view), unless the perspective is apparent from the drawing – other language should be minimized, except for some clarifying statements ("portions of the article not shown in the drawing form no part of the claimed design"; the environment of the design can be clarified if not adequately stated in the title) – environmental structures shown in the drawings must be shown in dotted lines, and must be expressly disclaimed (MPEP §1503.02: "the broken lines showing [article] are for illustrative purposes only and form no part of the claimed design") – if multiple embodiments are shown in the drawings, the applicant may distinguish them (MPEP §1504.05) – the specification may particularly point out a key feature of the claimed design, but this often limits the scope of the claim to

the recited aspects of the design (*McGrady v. Aspenglas Corp.* (1980)); thus, may be introduced during prosecution to avoid prior art

- Design patent claim: A design patent contains one omnibus claim: "The ornamental design for a [article] as shown" (MPEP §1503.01) – this one claim covers all embodiments shown in the figures, even where the design comprises an ornamental configuration of elements that can be used on many kinds of articles, e.g., a design to be used on several kinds of chinaware (*Ex parte Andrews* (1917))
- Design patent drawings: The drawings form the cornerstone of a design patent application – several drawings can be submitted to cover the use of the design in several embodiments (articles), so long as (1) they present a "unitary design concept" and (2) the designs are not patentably distinct (MPEP §1504.05) – the drawings must show the actual articles, not merely an abstract design theme (*Ex parte Guinzburg* (1925)) – the articles apart from the design should be shown in broken lines – the drawings should show all relevant external features of the claimed design; this includes unornamented surfaces of the article that might play a role (*Philco Corp. v. Admiral Corp.* (1961)) – however, duplicative drawings can be omitted (e.g., identical and symmetrical surfaces can be shown in just one drawing if the symmetry is apparent (*Moore v. Stewart* (1985))), and unornamented surfaces can be omitted if so described in the specification (MPEP §1503.02) – even a design patent for a computer icon may require multiple drawings (Guidelines for Examination of Design Patent Applications for Computer-Generated Icons (1996)) – in general, it is good practice to err on the side of too many drawings, because too few can render a specification incomplete – black-and-white photographs may be submitted as formal drawings so long as they do not depict environmental structure, and they cannot be combined with ink drawings in one application – otherwise, the rules of utility patent drawings apply: use the same stylistic conventions for surface features; e.g., color photographs and drawings can only be submitted under a granted petition (37 CFR §1.84(b))
- Design patent prosecution: Design patent prosecutors have the same Rule 56 disclosure duty as for utility patents, and can submit an information disclosure statement to raise potentially material prior art – 35 USC §§102-103 still apply in essentially the same form; however, the scope of prior art that may be relevant is broadened to include any design with a "substantially similar appearance," regardless of the functional nature of the article in which it is embedded (*In re Glavas* (1956): wallpaper design held anticipated by prior use on a piece of crockery) – also, the "grace period" following a public use is shortened from one year to six months (35 USCA §172)
- Expedited examination: As per 37 CFR §1.155, a practitioner can petition for expedited examination by conducting a preexamination search, submitting an information disclosure statement, and paying a fee

Chapter Nine (A): Provisional Patent Applications

- Overview: Provisional patent applications allow inventors to initiate the patent process with a minimum of expense and effort – this mechanism has been available to foreign applications for a while, and was extended to U.S. applicants in 1994 for competitive equality under the General Agreement on Tariff and

Trade (GATT) – the filing fees are considerably smaller than for full nonprovisional applications, because provisionals are only examined for adequate filing requirements – provisional patent applications are only effective for utility patents, not plant or design patents – provisionals are kept secret unless a converted nonprovisional patent based on the provisional issues, in which case the provisional becomes part of the file wrapper for the issued patent

- Requirements: A provisional application must have a cover sheet (37 CFR §1.51(c)(1), a specification sufficient to satisfy 35 USC §112, drawings where necessary to understand the invention, a statement of federal sponsorship if applicable (37 CFR §1.51(c)(1)(viii)), and the filing fee – the application *may optionally* include claims – the application must cite inventors, but since claims aren't required, the basis of inventorship is whether the inventor has contributed to the subject matter disclosed in the specification (35 USC §116, 37 CFR §1.45(c)); this may require naming a competitor in the provisional, though he can be removed for the nonprovisional filing in light of an exclusive set of claims – not required but may be provided: power-of-attorney document, assignment document, statement claiming small-entity status, translation of foreign references, and oath/declaration – the format of the specification is not required to follow the structure of a nonprovisional, but as noted, the specification must satisfy the written description, enablement, and best-mode requirements of §112 – information disclosure statements won't even be accepted by the USPTO for provisionals, and amendments may only be made if required by the USPTO
- Priority: The filing of a provisional application establishes a priority date for filing later nonprovisional applications, and this period does not run against the term of the ensuing patent (35 USC §154) – however, a provisional patent application always expire one year after filing, with no opportunity to extend or revive; thus, it must be "converted" by filing a full nonprovisional application – in former practice, the priority used to be irrevocably lost if not converted during the pendency of the provisional; this requirement was relaxed in the American Inventors Protection Act of 1999, but is still in effect for all foreign filings – in order to claim priority, the nonprovisional must refrence the provisional, feature at least one claim with antecedent basis in the provisional (35 USC §119(e)), and feature at least one common inventor (35 USC §119(e)(1)) – a nonprovisional may add new material and claim priority for the old material back to a provisional; this operates like a continuation-in-part application
- Claims: A provisional does not require claims – however, filing at least one claim is advised, because it is uncertain whether foreign patent offices will recognize a priority claim back to a provisional application with no claims – the claim should be very narrowly drafted: if the broad provisional claim that is narrowed in the nonprovisional, this may trigger *Festo* and narrow the scope of the patent claims
- Strategy for filing a provisional patent application: This type of application may be useful if an inventor wants to test the commercialization waters for a year prior to undertaking the costs of a nonprovisional patent application – may also be filed to secure priority in light of an imminent public disclosure – may also be used to secure the earliest possible filing date in light of the first-to-file rules of foreign patent practice – may also be filed to grant extended time to resolve inventorship

or ownership issues, or for prior-art searches and claim drafting; this extension can be exploited by registering the application with the Special Search Program of the European Patent Office (prior-art search results in three to six weeks) – provisionals benefit from reduced filing costs, but these costs are usually small, and are negated by the need to convert the application at a later date – also, the filing of a provisional allows the inventor to mark products "Patent Pending" as soon as possible –disadvantages: examination and issuance are delayed up to a year; if the provisional specification is ultimately deemed inadequate for priority, the applicant may have been lured into a false sense of security and may have unwittingly invalidated patentability; the provisional filing accelerates publication and the national-phase entry deadline; may raise inventorship issues (see above); a broad claim in a provisional may trigger *Festo* (see above)

Chapter Ten: Plant Patent Applications

- Overview: 35 USC §161: New, distinct, asexually reproducing plants can be patented – plant patents replace utility with distinctiveness – these patents are granted to encourage plant breeders to produce new species – such plants may also be the subject of utility patents, and sexually reproducing plants that do not qualify for plant patents may be protected by a certificate under the Plant Variety Protection Act (7 USC §2321 *et seq.*) – the patent covers the plant in its entirety, not any specific features
- Statutory requirements of patentable plants: Potentially patentable plants include cultivated sports, mutants, hybrids, and seedlings; all fungi and bacteria are excluded (*In re Arzberger* (1940)), as are all tuber-propagating plants – the applicant must have been the first to recognize its distinctive qualities (but joint inventorship is permitted, if each contributed to the recognition of distinctiveness) – the plant must have been grown in a "cultivated area," but the area doesn't have to belong to the applicant (*Ex parte Moore* (1957)) – the plant must be reproduced other than from seeds, such as by cutting, layering, budding, grafting, or inarching – some of the requirements for utility patents apply to plants: "on-sale" bar (the application must be filed within one year of selling or releasing the plant in the U.S.); publication bar (the plant must not have been descried in a printed publication more than one year prior to filing)
- Distinctiveness: Plant patent applicants must demonstrate "novelty" (distinctiveness) of the plant by differentiating it from every previously known plant by at least one distinguishing characteristic – this can be size; shape; color of leaves, fruit, or blossoms; "qualities" of fruit; maturation characteristics; or resistance to environmental and predatory characteristics; however, it cannot be proven by a variation caused by growing conditions or fertility levels
- Contents of plant patent application: Plant patents resemble utility patents in contents and order: title, cross-references to related applications, statement of federally-sponsored research, Latin name of genus ad species of plant, variety denomination, background, brief summary, brief description of drawings, detailed botanical description, claim, and abstract – the application must be submitted with an oath/declaration, and is usually submitted with a transmittal form and assignment documents

- Oath/declaration: In addition to the requirements of a utility patent oath/declaration, the inventor must aver that the applicant has asexually reproduced the plant, and that it was found in a cultivated area
- Title and variety name: The title should describe the plant ("apple tree," not just "apple") – the botanical name and description should comport with normal botany terminology and principles – a variety name should be suggested that is unique and complies with the U.P.O.V. Convention ("Convention for the Protection of New Varieties of Plants")
- Specification: The specification of a plant patent describe the plant in botanical terms, and focuses on its distinctive characteristics – this should include the genus and species of the plant, the growth traits, vigor, productivity, fertility, precocity, and botanical characteristics of plant structures – the colors of the plant can be precisely specified by reference to a color dictionary – the specification must also describe where the plant was found and how the plant was asexually reproduced (e.g., "by budding he sport onto root stock of peach trees"; see 37 CFR §1.163(a)) – the claim should not include unnecessary laudatory statements or advertisements for sale
- Claim: The claim of a plant patent is an omnibus claim to the plant described in the drawings and specification (MPEP §1610), e.g., "new and distinct variety of plant as described and illustrated" – the claim may call out distinctive characteristics of the plant, but these recitations may limit the scope of the claim
- Drawings: Plant patent drawings should be artistic, not technical, and should show all distinctive characteristics referenced in the specification – figure and reference numbers aren't needed – the drawings must be in color where color is a distinguishing feature, and color drawings may be submitted in watercolor or oil – color photographs are acceptable (and more commonly used)
- Specimens: A specimen of the plant may be requested by the examiner, but should not be otherwise submitted

Chapter Eleven: Electrical Patent Applications

- Overview: Electrical patent applications are stylistically similar to mechanical patent applications, especially since most circuit components can be claimed as a broad range of equivalents – these patents are usually more technical and more difficult for a nontechnical judge and jury to understand
- Other forms of protection: A circuit that embodies an algorithm may be alternatively claimed as software – any firmware embedded in the circuit can be copyrighted – also, the design of a circuit can be protected as a mask work under the Semiconductor Chip Protection Act of 1984 (37 USC §§901 *et seq.*) – copyright can also be extended for any expressiveness residing in the printed circuit board layout, embedded audiovisual elements (an encoded sound or image file), the product packaging, and documentation
- Claim considerations: Claims to electrical inventions are ordinarily claimed functionally, due to the wide variety of equivalent structures for any function – e.g., "means for producing an output voltage proportional to an input voltage" could be structurally claimed as a restive voltage divider, potentiometer, reactive voltage divider, transformer, or operational amplifier – the CCPA widely

endorsed the use of means-plus-function elements for electrical inventions (*In re Knowlton* (1973) dealt with the following claim:

> A linked list processor comprising:
>
> a memory;
>
> means for establishing blocks of storage within said memory;
>
> means for specifying fields within said blocks for storing data signals and linking signals, said fields being of arbitrary size and location within said blocks;
>
> a plurality of base registers for storing linking signals to prescribed ones of said blocks; and
>
> means for accessing and processing the contents of any prescribed field in said memory.

The USPTO rejected this claim as overbroad and claiming a huge array of embodiments, but the CCPA reversed and found this claim properly drafted and supported by the specification – moreover, electrical arts are much more predictable than chemistry or biotechnology, so a very broad genus can be supported by only a few species embodiments, or even one (*Spectra-Physics v. Coherent Inc.* (1987))

- Claim drafting: The claims should be drafted to cover potentially infringing embodiments, so the broadest claims should exclude nonessential components like power sources and input/output devices that a competitor might omit from a designed-around package – the amount of prior art is vast, and cannot be fully studied in any novelty search; therefore, the practitioner should include claims of varying scope so that at least some narrow claims will issue – the elements of the claims may be described as cooperating electrically, mechanically, or both – patent preparation is very typical, involving an understanding of the invention, a novelty search, rough drafting of the broadest claim in purely functional language, an outline of the claim scope, and drafting of progressively narrowing claims with increasingly specific structure
- Drawings: Most electrical inventions can be adequately described as functional block diagrams, and these are generally preferred by the USPTO and CCPA (*In re Ghiron* (1971)) – circuit diagrams, flow diagrams, and timing diagrams may also be included – the drawings should focus attention on the novel features, and every claimed feature should be shown in at least one drawing – the level of ordinary skill in the art is presumed to be very high, and an average practitioner should be able to suggest many components for any claimed feature; thus, the drawings need not be overly detailed (*In re Knowlton* (1973): drawings undeniably complete, but criticized for not being sufficiently "concise") – the elements should be shown to cooperate, especially where the interaction is unconventional; if the circuit timing is unusual and important, a timing diagram may be needed – where the circuit carries out a process, a flow diagram is helpful for illustrating the inventive concept; this also helps broaden the patent scope beyond the apparatus claims – these kinds of diagrams are also useful for providing an easy-to-understand overview of the invention for the benefit of a non-skilled jury – the drawings should comply with the usual requirements of patent drawings (37 CFR §1.84(n)), but these requirements will be substantially met by using regular

conventions of circuit diagrams – components may be labeled with specific part numbers; these may have varying breadth, from identifying generic logic families, sets of components, or a specific component – of course, these classifications should be fully described in the specification and mirrored in the claims

- Element reference numbers: The components of most inventions are numbered on the drawings and referenced by number in the specification (and sometimes the claims) – conventional circuit diagrams usually just refer to each component by its functional name ("resistor 1," "resistor 2," etc.); this method can be used in electric patent references – this can result in a much clearer specification to those of ordinary skill in the art – it can also lead to a more concise specification, since many common elements need no more specific description than simply the name
- Specification: The requirements of 35 USC §112 for written description, enablement, and best mode apply as for any other kind of invention – because functional claim style is very common for electrical inventions, the specification should suggest a wide range of alternative equivalents for each component – although the level of ordinary skill in the art is presumed to be high, the specification should still be written in very basic terms so that it can be read by a non-expert jury – the practitioner should specifically avoid limiting the invention to an analog, digital, or computer implementation; although regular engineers recognize these embodiments as equivalent, an examiner may disallow expansion of the invention by amendment as an attempt to add "new matter" (*In re Rasmussen* (1982)) – if an element is well-suited by specific preexisting equipment for the best mode or enablement requirements, the equipment should be fully identified in the specification ("A device suitable for use as the phase locked loop circuit 44 is available as 'model MM55106 PLL frequency synthesizer' from National Semiconductor Corp. of Santa Clara, CA."); also, known designs in patents or other references can be expressly included in the specification ("The circuit for a 23-channel, dual crystal frequency synthesizer is given at pat 4-25 of the National Semiconductor *CMOS Databook*, 1977, which is incorporated herein by reference.")

Chapter Twelve: Patent Applications for Software and Methods of Doing Business

- "Software" defined: This term is alternatively used to describe different but interrelated concepts: a series of set written in a programming language, the translated (compiled) set of computer-readable instructions that form an executable, and the interactive product of those instructions, including the user interface and the functional results of mathematical algorithms – software is more definitively differentiated from the hardware that comprises the physical components of the machine, though these concepts are also interrelated
- Other forms of protection: In addition to being patentable, software may be amenable to other forms of protection to cover different features – a design patent may cover the ornamental design of certain graphical elements of the software (e.g., icons), and may be given broader scope than a copyright for the same artistic expression – the software, documentation, etc. are covered by copyright, though this only limits copying/adaptation/etc. of the source material, and does

not cover the inventive concepts of the software or block independent invention – trade secret protection may apply to certain algorithms, but it's difficult to enforce this, because the software is easily reverse-engineered – mask work protection may apply to the physical implementation of the software as an integrated circuit – thus, utility patents for software are valuable for securing an exclusive right to the inventive subject matter

- The history of software patents: 35 USC §101 excludes certain kinds of ideas from the scope of patentable inventions, including mathematical expressions, mathematical algorithms, printed matter, and mental steps – on this basis, the USPTO historically rejected all patent applications for algorithms as falling outside the statutory classes of §101; however, the CCPA was more open to considering patentability for software (*Gottschalk v. Benson* (1972)) – for a while, the CCPA utilized a two-step test to determine whether an invention was useful or an unpatentable mathematical concept: (1) did the invention directly or indirectly recite a mathematical algorithm? if so, (2) does the patentee seek to "wholly preempt" the use of the algorithm in any context? (*In re Freeman* (1977)); application of this test allowed some software related to "real-world processes" to be patented (*Diamond v. Diehr* (1981)) – the CAFC refined the CCPA test to allow patents for algorithms that had some connection with a physical process, either operating on sensor measurements or controlling machinery (*In re Grams* (1989)) – eventually, the CAFC completely abandoned these tests, holding that software was inherently a patentable "process" and must be considered for patentability (utility) on the same basis as any other invention (*State Street Bank & Trust Co. v. Signature Fin. Group, Inc.* (1998)) – simultaneously, the CAFC vacated a commonly-cited rejection of business methods as inherently unpatentable – thus, software that achieves a useful result is now patentable (*AT&T Corp. v. Excel Communications, Inc.* (1999): patentability affirmed for a software algorithm for logging long-distance calls)
- MPEP guidelines for software patentability: MPEP §2106 sets forth the USPTO's current guidelines for the patentability of software, which instructs examiners to follow a routine set of steps: determine what the applicant has invented, conduct a prior art search, determine whether the claimed invention is patentable under §101, evaluate satisfaction of the requirements of §112, and determine the novelty and nonobviousness of the invention under §§102-103 – this section also sets forth guidelines for determining patentability under §101 – all inventions must fit within a statutory class – patentable subject matter includes functional descriptive material embedded in computer-readable media, a computer program (process) that results in the manipulation of physical objects, data representing physical objects, the characteristics of the host computer, or the data processed by the computer; i.e., the algorithm is patentable if it has a "significant use" – unpatentable subject matter includes "mathematical ideas," laws of nature, and nonfunctional descriptive material (including raw data structures) – product claims that encompass all mechanisms are considered process claims – field-of-use preambles do not limit the scope of the claim – additional guidelines have been published as the PTO Examination Training Materials on Computer-Related Inventions (1998)

- Identifying the prior art: Most information relevant to software inventions comes from non-patent literature, especially the publications of the Association for Computing Machinery (ACM) and Institute of Electronics and Electrical Engineers (IEEE) – databases of software prior art may also be helpful
- Software patent claim types: Software can be fit within the statutory classes of process, machine, or article of manufacture – when claimed as a process, the software is usually presented as a preamble citing the field of use, pre-algorithm activity for gathering data, algorithm activity and output, and post-solution activity – as usual, independent claims recite these steps in broad functional language, while dependent claims suggest specific options for filling each means
- Software apparatus claim: This claim style implies that a general-purpose computer has become a special-purpose machine by the inclusion of a software algorithm – the physical components of the machine are often claimed in means-plus-function language – thus, the preamble reads: "A data processing system comprising…" and sets forth the components of a typical computer (at least one input device; at least one output device; some memory; some physical storage; one or more processors…) – the actual software components are described as means-plus-function elements – this style has a good track record for patentability (*In re Iwahashi* (1989)), but is now being interpreted more stringently; if all elements are claimed as "means for," the USPTO may construe the claim as to a method (*In re Akamatsu* (1992)) – also, a claim to a "means for" performing a function may cover only special-purpose circuits manufactured for this process, rather than general-purpose processors that carry out the step (*WMS Gaming Inc. v. Int'l Game Tech.* (1999) (not sure if this is true!)) – see U.S. Pat. Nos. 4,399,504 and 4,652,856
- Software method claim: This claim style characterizes the algorithm as a series of steps, which is quite easy and natural – usually begins: "A method in a data processing system for…, the method comprising the steps of:…" – see U.S. Pat. Nos. 4,482,956 and 5,930,775
- Software product claim: This claim style characterizes the algorithm as the "program product" of a compiler or development process, reciting the invention as a "system" or "an article of manufacture comprising…" – see U.S. Pat. Nos. 4,887,204 and 4,864,492
- Software patent claim tactics for infringement: A practitioner seeking to draft a patent to ensnare infringers should consider how a competitor might infringe or design around the invention, and should attempt to ensnare the infringer directly rather than contributorily – unfortunately, when claimed as a process, the infringing algorithm is executed by the end user, and when claimed as a machine, it becomes infringing only when the end user converts his machine to the patented machine; in either case, the patentee must sue potential customers along with the competitor – by contrast, "program product" claims are directly infringed when the competitor manufactures and distributes the same algorithm as a product – hence, many software patents are now written as a "system" comprised of software modules, without any supporting hardware – U.S. Pat. No. 4,866,610 claim 1:

A computer software system having a set of instructions for controlling a general-purpose digital computer in performing a desired function, comprising:

a set of instructions formed into each of a plurality of modules, each module comprising:

a communications process;
a computational process;
a data storage process; and
a feedback process.

The patent may be also be written in anticipation of maximizing infringement damages – royalty calculations are often based on the total value of the infringed invention; thus, including major hardware elements can increase the base value of this calculation – since this tactic suggests an opposite trend to the infringement-maximizing tactic, the invention should be claimed in both methods

- Statutory subject matter for software patents: Although recent CAFC decisions have limited §101 rejections, examiners may still try to assert them – several tactics for avoiding this response are available – first, remove all mathematical language from the specification (if necessary, recite formulae only as an alternative to functional process claims); describe each component in functional language (*In re Pardo* (1982): "a process f operating a general-purpose data processor to execute formulas in an object program comprising a plurality of formulas, comprising the steps of: (a) examining each of said formulas; (b) executing said formulas designated as defined; and repeating steps (a) and (b)") – second, claim the invention as a tangible apparatus (shift registers, keyboard, monitor, etc.; recite the invention as a "computer-based method" or a "system") – third, relate the process to a physical transformation, such as the transformation of a "signal" from one physical state to another; this is a patentable transformation, even if controlled by software instructions (*Arrhythmia Research Tech., Inc. v. Corazonix Corp.* (1992)) – fourth, relate the solution to significant post-solution activity; while "significance" is unclear in light of conflicting precedent (*Safe Flight Instruments Corp. v. Sundstrand Data Control, Inc.* (1989)), but a process that produces a "useful, concrete, tangible result" should be allowable (*State Street Bank & Trust Co. v. Signature Fin. Systems* (1998)) – finally, include a field-of-use clause that demonstrate the real-world utility of the invention (*AT&T Corp. v. Excel Communications Inc.* (1999): "A method for use in a telecommunications system in which interexchange calls initiated by each subscriber are automatically routed over the facilities of a particular interexchange carrier associated with that subscriber")
- The disclosure: Satisfying 35 USC §112 for software inventions can be difficult, because these inventions are often interdisciplinary; a patent for a bioinformatics algorithm requires estimation of the "ordinary skill in the art" of software, genetic engineering, and maybe even biochemistry – MPEP §2106.01 ("Computer Programming and 35 USC §112") instructs examiners generally to apply enablement from the perspective of a skilled programmer, but special knowledge of other fields can sometimes be assumed as within the "ordinary skill in the art" (*In re Naquin* (1968)) – as usual, the disclosure must teach the invention

sufficiently to allow use without undue experimentation (*White Consol. Indus., Inc. v. Vega Servo-Control, Inc.* (1983)) – if the function of the algorithm is sufficiently described, disclosure of the source code is not necessary either for enablement or "best mode," but may be advisable to avoid the issue in litigation – the detailed description of the specification usually features several levels of detail: (1) the system context of the invention: specify the kind of computer that can run the software, and the necessary hardware components involved ("This invention is executable on an XYZ computer, running a 538 TDY operating system, which includes a CPU, memory, I/O resources, and a user interface including a keyboard and mouse"); this can also be recited as a block diagram – (2) major component overview: describe each of the modules of the algorithm and how they interoperate, including data structures and memory blocks; again, a block diagram is helpful (see U.S. Pat. No. 4,890,240 Exhibit 12-1) – (3) major component details: describe the internal workings of each component, possibly with source code to avoid any enablement issues; this isn't necessary, but the functional details must be disclosed, and can't be withheld under a trade-secret claim (*White Consol. Indus. v. Vega Servo-Control* (1982)) – an intermediate approach is to disclose the algorithm as pseudocode (see U.S. Pat. No. 4,890,240 Exhibit 12-3), or as a flow diagram (see U.S. Pat. No. 4,890,240 Exhibit 12-4) – a flowchart is often necessary for internationally-filed applications, where software can only be claimed as a process

- Standard terminology: Examiners may object to terms like "binding," "echoing," or "executing" as vague and undefined – reference can be made to *Sippl's Computer Dictionary* or the *Dictionary of Computing* as well-recognized technical dictionaries
- Drawings and program listings: As noted above, software drawings may include source code, pseudocode, flowcharts, or block diagrams showing interoperating software modules/objects, network communications, or a hardware/software interface (e.g., in an apparatus claim) – international standards exist for flowchart symbols in representing computer processes (see ISO 5807) – code can only be included as a drawing if it consists of 300 lines or fewer with 72 characters per line; longer source code must be submitted as a "computer program listing appendix" on CD-ROM (37 CFR §§1.52(e) and 1.96(d)), and must be referenced in the specification – this appendix does not become part of the written record of the patent, but will be accessible to the public – of course, computer code submitted either way retains its copyright, and a copyright notice can be affixed (the exact wording of the notice is set forth in 37 CFR §1.71(e))

Chapter Thirteen: Patent Applications for the Chemical Invention

- Overview: Patenting chemical inventions requires some special considerations due to the inherent unpredictability of the field – other considerations will be necessary for patenting biochemistry inventions (see next chapter) – of course, the composition must be novel; it is not patentable if its existence was known but its utility was not – however, new purification techniques may yield a novel highly-purified sample of a known compound, thereby imparting patentability

- Specification – written description: The chemistry invention claimed in a patent application must be sufficiently described to demonstrate that the applicant was in possession of the invention at the date of filing; thus, the practitioner should first draft the broadest claim, and then write the specification sufficiently to support that claim – the specification often includes the broadest claim verbatim to guarantee that the claim has antecedent basis in the specification – alternatively (or additionally), the specification may paraphrase the broadest claim in less technical language for the benefit of a non-expert judge and jury – the invention should be described in considerable detail (*Fiers v. Revel* (1993): claims relating to DNA rejected as not sufficiently described because the patentee did not include enough detail about structure, sequence, formula, or definitive physical or chemical characteristics) – claims for a genus should be supported by an exhaustive list of species compounds, both to satisfy the written description requirement and to ensnare a broad range of equivalents (see *In re Ruschig* (1967)); the most preferred species should be dependently claimed – in certain cases, it may be possible to describe a genus fully by listing elements *not* in the genus (*In re Johnson* (1977)), or by claiming all compounds satisfying a numerical range of some characteristic (*In re Wertheim* (1976))
- Specification – how to make: A chemical compound invention is only enabled if the specification teaches both how to make it and how to use it, in detail sufficient for one of ordinary skill in the art to practice the invention without undue experimentation – well-known concepts can be incorporated by reference (MPEP §608.01(p)) – the method of making the compound should first specify starting materials (both generically and specifically); if the starting materials are also novel, the specification must also teach how to make them as well – commercially available starting materials can be described by supplier – if a starting material is described by a reasonably fixed trademark or trade name, that can be used – if not, the supplier may be able to supply a data sheet describing its current composition that can be incorporated; the material might also be patented, in which case the patent can be incorporated by reference – the method of making must also specify reaction conditions, preferably with broad ranges (both effective and preferred) – the end products of the "method of making" might be many variations in a genus; thus, a claim to the chemical composition as a genus should be supported by working examples – the examiner might attempt to limit the scope of the invention to the working examples, but this is improper (*In re Borkowski* (1970)) – if only a few experiments have been conducted, it may be wise to file an application with few working examples immediately, and later file a continuation-in-part citing new data – because this art is unpredictable, prophetic examples are generally inadequate, but these can be included as a "last resort" or stopgap measure
- Specification – utility and how to use: The specification must teach how to use the invention to satisfy both §101 utility and §112 enablement – the utility has to be "real-world," i.e., the composition must be more than a mere research material, or an intermediate compound for preparing a known compound (*Brenner v. Manson* (1966)) – if the utility of the composition would be apparent to one of ordinary

skill in the art, this section can be brief; but if the composition is asserted to have "biological activity," the requisite level of proof considerably rises

- Specification – best mode: The best mode of using the invention must be included, but need not be labeled as such, unless it is one of a vast number of disclosed examples – this requirement applies to every element of every claim, and can be satisfied by fully describing the elements in turn – this may require identifying preferred starting materials, and even the supplier of each (*Chemcast Corp. v. Arco Indus. Corp.* (1990)) – while some cases suggest that the disclosure requirement is limited to the "invention as claimed," good practice suggests disclosing everything to ensure that this requirement is satisfied
- Claims: A novel composition may involve many distinct inventions: the compound as a structural entity, the compound having desirable properties, methods of making and using it, other compositions containing the novel composition, and kits of reagents including the composition – if claimed too broadly, the examiner very often issues a restriction requirement, possibly citing a multiplicity of distinct inventions; prosecution costs may grow exponentially, so claim strategy is important – Markush groups are very common in chemical composition claims, but the claimed members must share a common property; dependent claims to the preferred species are highly recommended, in case the group is found to lack novelty (prior existence of even one element can invalidate the whole Markush group) – product-by-process claims are useful where the structure of the composition is unknown, and may cover the product even when made by a different process (*Scripps Clinic & Research Found. v. Genentech* (1991)) – functional expressions are useful ("incapable of forming a dye with said oxidizing developing agent"), and a novel composition should be alternatively claimed by its novel functions (*Ex parte Brian* (1958)) – broad coverage of chemistry inventions may be very difficult, so careful claim drafting is important: use open-ended terms like "mixture"; avoid unnecessary limitations; and if the compound can be made by combining ingredients that form intermediates with each other, claim all possible combinations of these starting reagents (*Exxon Chem. Patents, Inc. v.. Lubrizol Corp.* (1995)) – finally, the unpredictability of the field can be helpfully referenced in defeating an obviousness rejection; good practice suggests including evidence of unexpected effect in the specification

Chapter Fourteen: Biotechnology Patent Applications

- Overview: Biotechnology includes "the creation of new varieties of plants, new animal breeds, and new microorganisms, either by traditional selection methods or by new methods of genetic engineering, that is, by methods of modifying genes of animals, plants, and microorganisms, by introducing an artificially modified genetic material, to provide new products, and new processes for using or producing such products" – this field poses its own patentability challenges – two main areas of biotechnology patenting at present: new compositions (both a protein and the hybridoma that produces it) and useful processes (diagnostics, therapeutics, research techniques) – common claim categories: cDNA/rDNA, proteins, monoclonal antibodies, methods of blocking monoclonal antibodies, protein receptors, anti-sense DNA, recombinant vectors, cell lines, methods of

expressing genes to produce a purified protein, transgenic animals, kits, and pharmaceutical compositions – similarly, a new protein can include claims to the isolated protein, the protein/binding-site complex, a processed/effective form of the protein, the DNA encoding the protein, expression systems and methods, methods of using the protein, pharmaceutical compositions containing the protein, the use of the protein as a probe, antibodies reactive to the protein, methods of purifying the protein, and assays for determining protein level

- Other forms of protection: Novel plants can be patented under the Plant Protection Act of 1930 (for asexually reproducing plants), or the Plant Variety Protection Act of 1970 (for sexually reproducing plants, excluding bacteria and fungi); the critical requirement in both cases is distinctiveness – the threshold of protection is lower (nonobviousness not required, but must be "distinguishable from any other variety the existence of which is publicly known or a matter of common knowledge at the time of the filing of the application" (7 USC §2402)), but the scope of protection is very limited – the applicant may have to make a seed deposit, but these are solely for documentation, and are not released to the public; but the PVPA has a research exemption, and compulsory licensing schemes are mandatory – of course, the plant can still be utility-patented if it meets the criteria for patentability
- "Invention" in biotechnology: Because these inventions usually operate in extremely complex environments, they are often claimed functionally, or as a process (U.S. Pat. No. 4,738,927: "A gene comprising a recombinant DNA molecule encoding a polypeptide possessing biological activity of interleukin-2, wherein said biological activity is promotion of growth of a cytotoxic T-lymphocyte cell line, where said polypeptide has 132-134 amino aids") – accordingly, the invention may be claimed in many ways, which is helpful for patenting but detrimental for patentability/infringement searching – disclosing and claiming all of the related inventions cited above is very difficult and expensive, and creates many opportunities for avoiding the patent
- Patentability: Biotechnology faces fewer patentability problems than other forms of high-tech inventions like software and business patents (*Diamond v. Chakrabarty* (1988)); even issues over patentability of new multicellular organisms that initially prompted a backlash have been squarely resolved (see U.S. Pat. No. 4,736,866 to the Oncomouse) – of course, the invention must satisfy 35 USC §§101-103: the invention must have some utility (can't merely be useful for identifying something else that might be useful)
- 35 USC §101 (utility): The threshold for most biological utility is low; an assertion of utility for a specific purpose (e.g., to treat a specific disease) is usually sufficient, though more general claims like "anti-tumor substance" are not – the USPTO may require additional proof if (1) the claims are incredible or unlikely (this places the burden of proof on the applicant), or (2) if the examiner specifically believes the utility claim is not credible (this places the burden of proof on the examiner) –for biotechnology, the standard is higher, and utility rejections are more common (e.g., *in vitro* efficacy is not necessarily proof of *in vivo* efficacy) – MPEP §2107.02 ("Special Considerations for Asserted Therapeutic or Pharmacological Utilities") states that *in vivo* data is not required

if such use is credible in light of *in vitro* data – however, inventions with asserted efficacy specifically for humans have a higher threshold (*Cross v. Lizuka* (1985)), which the practitioner may have to overcome by asserting, among other arguments, the incompatibility of full clinical trial data with the early disclosure requirement of the U.S. patent system – more recent guidelines (66 Fed. Reg. 1092 (2001)) lower this threshold to some extent: proof of efficacy and safety of an agent for humans are not required; utility is adequately stated if it is apparent to one of ordinary skill in the art, which usually hinges on a finding of a "reasonable correlation" between the biological activity of an agent and its asserted utility; if a reliable animal model for a condition is not available, the application can still stand if the presented data is "reasonably predictive" of activity in humans; FDA approval of a clinical trial is *per se* "reasonably predictive" of utility – an example of inadequate utility: a nucleic acid sequence whose only use is as a probe for the full-length gene

- 35 USC §102 (novelty): The same rules, concerns, and best practices of novelty for other kinds of invention apply to biotechnology – additionally, a common basis for rejected novelty in biotechnology inventions is that the claimed process occurs in nature (sometimes incorrectly cited as a 35 USC §101 rejection), or that the applicant claims a portion of a naturally-occurring substance or gene – generally, a naturally-occurring product can be patented as a more highly purified sample than occurs (or is possible) in nature; the claim should recite the protein as "biologically pure" or "isolated" (*In re Bergstrom* (1970)), or as a "crystalline compound" – similarly, a metabolite of a prior-art drug can't be newly patented, unless it is synthesized in purified form (*Schering Corp. v. Geneva Pharms., Inc.* (2003))
- 35 USC §103 (nonobviousness): Obviousness rejections are almost ubiquitous for biotechnology applications, and usually the practitioner will not have been able to find it in a routine novelty search – accordingly, the USPTO allows increased flexibility in §103 avoidance arguments in biotechnology – the application can be drafted defensively to anticipate such rejections with proof of secondary nonobviousness indicators: unexpected results; prior art "teaching away" from the invention; undue experimentation needed for success; the invention might have been "obvious to try" but was only recommended in very general terms – also, the USPTO has abandoned a policy of rejecting claims to genes that encode known proteins, because the CAFC rejected this argument in light of the degeneracy of the DNA transcription process: "there are a vast number of nucleotide sequences that might code for a specific protein" (*In re Bell* (1993)) – more difficult to overcome are rejections of claims to monoclonal antibodies in light of published methods by Kohler and Milstein for producing monoclonals (*Nature*, 1975), or *In re Durden* (1985), where patentability was denied for a novel compound synthesized by using a known process with a novel starting product – traversal arguments could focus on unique aspects of the monoclonal screening process, e.g., a selection step that focuses on a characteristic other than binding affinity – the danger in such traversal attempts is that arguments like unpredictability may be cited by the examiner to maintain a rejection of the broad claim as non-enabled in light of the asserted unpredictability – fortunately, the CAFC and USPTO have

retreated from this position (*In re Ochiai* (1995)), and Congress passed 35 USC §103(b) to instruct the USPTO not to reject an obvious method of making a novel biological product – also, the CAFC has affirmed that a novel composition and its method of use may be claimed in the same application (*In re Pleudemann* (1990)), reversing a trend of examiners issuing restriction requirements for such conjoined applications

- 35 USC §112 (written description): As with other patent inventions, biotechnology can only be patented by a specification that "contains sufficient disclosure to make it clear to persons skilled in the part that the applicant possessed the subject matter claimed" – again, it is recommended to incorporate all of the claim language into the specification, and the limitations of every dependent claim should be included but indicated as optional (*Martin v. Mayer* (1987)) – the description for a material, including a DNA sequence encoding a specified protein, must sufficiently describe its structure, formula, or chemical and physical properties (*Fiers v. Revel* (1993)) – the CAFC has held that disclosing the complete sequence of a protein satisfies the written description requirement for a claim to any DNA sequence encoding it; but specifying only the amino acids comprising a binding site of a protein does not satisfy the written description requirement for a claim to the whole protein (*In re Wallach* (2004)) – also, sufficient written description of a mouse antibody does not allow the applicant to claim the human version of the same antibody, nor the genus comprising both of them (*Noelle v. Lederman* (2004)) – in general, it's good practice to cite the structure and sequence listing of any claimed protein or DNA sequence, and a claim to a genus should sufficiently describe many species within the genus
- 35 USC §112 (enablement): Enablement is difficult to satisfy in biotechnology due to the difficult and unpredictable nature of the field – factors relevant to whether a disclosed invention requires "'undue' experimentation" were cited in *In re Wands* (1988) to include: the amount of experimentation necessary, the amount of guidance presented, the availability of working examines, the nature of the invention, the state of the prior art, the relative skill of the average practitioner in the field, the predictability of the art, and the breadth of the claims – however, these guidelines are difficult to apply, and so "'undue' experimentation" is determined on a case-by-case basis – in general, the application should be sufficient to support a technical publication in the field – including working examples are helpful, as is (to a lesser extent) including prophetic examples, and several should be included for securely satisfying the enablement requirement – if the claims are worded in overly broad style (claiming an element "or biologically functional equivalent thereof"), they may be rejected as non-enabled (*Ex parte Maizel* (1992)) – some examples of lack of enablement due to the perceived unpredictability of the art: a gene encoding a known protein product cannot be claimed without sequencing the gene (*Fiddes v. Baird* (1993)); a human protein gene cannot be claimed by citing the sequence of the monkey gene, because the degree of homology is unknown; disclosing a DNA sequence that encodes a protein does not allow the applicant to claim any protein with the same biological activity (*Amgen, Inc. v. Chugai Pharm. Co.* (1991)); a claim to a protein that

required cleaving it from a conjugate protein is non-enabled unless a method of carrying out the cleavage is also disclosed (*Genentech, Inc. v. Novo Nordisk A/S* (1997)) – in light of these holdings, it's good practice to draft an extensive specification with many examples and much supporting data

- 35 USC §112 (best mode): As with other inventions, the applicant is required to teach the best mode of making and using the invention known to him at the time of filing – this requirement fails only if the applicant conceals a best mode (*Hybritech, Inc. v. Monoclonal Antibodies, Inc.* (1986)) – this requirement applies even if the best mode "known to" the applicant was invented by someone else (*Aktiebolaget Karlstads Mekaniska Werkstad v. U.S. Int'l Trade Comm'n* (1983)) – because this rejection is extremely hard to support, examiners rarely make it, and grant deference to the applicant in assuming it has been satisfied (*In re Bundy* (1981))
- Deposits: Inventors of biotechnology inventions that are self-replicating and can't be adequately described in text (e.g., complex biological organisms) can satisfy the written description requirement by depositing a sample with a biomaterials depository, and referencing it in the specification (the accession number, name and address of depository, date of deposit, and identifying description of the material) – the circumstances where this is *required* are not well-defined (*In re Reinhard* (1985): deposit not required for material isolated from deep-sea creatures because the applicant described where to find the organisms) – the material must be self-replicating, and the applicant must demonstrate viability of the deposited sample; the depository will endeavor to retain viability, but if this fails, the applicant/patentee must renew the deposit – the sample will be kept confidential until/unless the patent issues – the effect of a deposit is *per se* satisfaction of all requirements of §112
- Sequence data: The USPTO provides rules for standardizing the formatting of nucleotide and amino acid sequence data (37 CFR §§1.821-1.825 and 37 CFR §1.52(e)); must be submitted in a computer-readable form using standardized symbols with sequence identification numbers – the sequence may also be shown in a figure, so long as the requirements of 37 CFR are met, and as long as the inventor submits a statement that the "drawing" of the sequence listing is identical to the electronic copy – continuing applications (including CIPs and divisionals) can incorporate by reference a sequence listing previously disclosed and supplied to the USPTO
- Claims: Claims for biotechnology inventions must meet the same requirements of definiteness (under 35 USC §112) as for other inventions – many such claims are rejected as indefinite, especially those claiming a genus where the applicant has only satisfied the §112 requirements for a few species – it is difficult to craft broad and allowable biotechnology claims that cannot be designed around: a claim to a protein with a fully-specified amino acid sequence can be avoided by changing some nonfunctional parts of the protein, yet a disclosure and claim to the functional part of the protein may fail the written description requirement; instead, the applicant might claim "protein X having the ability to catalyze the reaction Y," and then claim the method of catalyzing Y by using X or an equivalent – in fact, a claim to a protein need not disclose the complete DNA

sequence, but can instead teach in the specification how one might discover a DNA sequence encoding for the protein – even apparently broad claims may be unforeseeably narrowed (*Genentech, Inc. v. Wellcome Found.* (1994): claim to "a DNA isolate consisting essentially of a DNA sequence encoding human t-PA" was limited at trial to naturally-occurring human t-PA, and not to cover DNA encoding synthetic t-PA with a few nonfunctional changes from natural t-PA) – while the USPTO considers proteins with distinct nucleotide sequences to be distinct proteins, it allows up to ten independent, distinct nucleotide sequences to be claimed in one application – the USPTO also routinely issues restriction requirements for applications claiming a compound, a method of making it, and a method of using it

- Biotechnology claim styles: Biotechnology claims often use functional language because of the difficulty of describing very complicated materials in structural language – Markush groups are common, but enablement must be shown for a substantial and representative number of species in the genus – Jepson claims are frequently used, but have the same problem as in other contexts that the background recited in the preamble is admitted to be prior art; accordingly, both the USPTO and practitioners are moving away from Jepson-style claims – "product-by-process" claims are also frequently used, particularly in light of *Scripps Clinic & Research Found. v. Genentech, Inc.* (1991), holding that the described process is not a limitation of the product claim – method claims are both common and important: 35 USC §271 allows enforcement of a method claim against an importer of the product who used the patented method overseas – also, some foreign patent practices disallow claims to pharmaceuticals or foodstuff, but allow patents for methods of making them

Chapter Fifteen: Preparing Foreign Patent Applications Based on a U.S. Application

- Overview: Because the enforcement of a U.S. patent is limited to acts within the U.S., the patentee must file foreign patent applications to receive worldwide protection – this chapter discusses how to convert a U.S. application into a foreign patent application, with an emphasis on cost-effective prosecution tactics; while countries differ in their requirements, these guidelines should be generally applicable
- The choice of foreign filing: Foreign patent prosecution and maintenance is costly compared to U.S. practice, so the choice of when and where to prosecute outside the U.S. should be undertaken carefully – while many applicants simply file the U.S. application abroad, that process may have difficulty squaring with differences between U.S. and foreign patent laws, so time and money should be spent to revise the U.S. application in light of foreign patent practice
- Foreign filing options: The application can always be filed directly with the national office of any country, which is the quickest way of obtaining a patent there, but this accelerates patent costs – some of the costs can be defrayed by relying on a regional treaty, where prosecution begins in one centralized office on behalf of several countries; the largest regional treaties are the European Patent Convention or EPC (a treaty among a body of European countries for unified and

reciprocal respect of patent rights; the applicant files once with the EPO, and designates [and pays a fee for] each member state in which he wishes to prosecute the application), the Eurasia Patent (covering Russia and some former USSR states), the ARIPO Patent (covering some countries in Africa), and the OAPI Patent (covering other nations in Africa); or applications within each of several nations – even more efficient, and the most common choice in practice, is reliance on the Paris Convention or PCT (a worldwide treaty to which all major countries are signatories except for Taiwan) – in any event, the application must be filed within twelve months of the U.S. filing date, and at some point the application must be transferred to the national offices where prosecution will conclude and result in a national patent – if an applicant is not relying on the PCT, then as per 35 USC §184-185, the applicant must file a request for a "foreign filing license" from the USPTO authorizing the foreign filing; failing to obtain such a license before the non-PCT foreign filing can invalidate the U.S. patent – however, the foreign filing license ordinarily accompanies the U.S. filing receipt as a matter of course

- Foreign filing procedure: A PCT application can be filed for approximately $1,500 (again, a priority claim based on a U.S. application is only valid if the PCT application is filed within twelve months of the U.S. application) – this filing gives the applicant the capability of forestalling the designation of national-phase countries by an additional eighteen months; thus, an applicant may achieve a maximum day of thirty months between initial filing and undertaking hefty national-phase filing costs – during the 18-month window, the PCT application is given a cursory initial patentability search, and if the applicant so requests, a very brief examination; the applicant may designate either the USPTO or the EPO as the examining body (the EPO is regarded as somewhat more thorough, and it's almost pointless to have the USPTO examine both its direct filing and the international filing) – this initial search and examination is usually relied upon in each national-stage country, so this effectively provides a head start for national protection in each country – however, the cursory nature of the examination, and the *Festo*-like estoppel that can derive from the amendment of a PCT application, may be tactical reasons to avoid requesting international examination – after eighteen months, each designated national office may begin examination, but some hold the application in abeyance until the applicant actually files a request to have it examined (Canada will so hold an application for a maximum of five years, Japan for seven years, etc.), and even further delays can be achieved by filing for extensions of time during prosecution
- Foreign filing contents: PCT-related documents must usually be filed on A4 paper, and with a Request signed by (only) one applicant or an empowered attorney; if an assignment of rights applies to foreign applications, a copy should be filed with the foreign application (but if the foreign application contains new matter, a new assignment should be prepared) – foreign patent applications may usually be filed in the name of the assignee and the inventors, rather than solely naming the inventors as in the U.S. – every national-phase application must be filed by a qualified patent practitioner of that country – also, the patent application must be translated into the native language; this is a costly process that ordinarily

takes four weeks, though expedited translation is available (at an even greater cost) – if the application is filed in several countries that use the same language, the translation prepared by one can be forwarded to the others, who will only assess a surcharge for verifying the accuracy of the translation

- Revising the U.S. specification for foreign filing: While the specification of a U.S. application is ordinarily quite verbose (due to the requirements of §112), foreign applications should be reduced by editing for several reasons: less support of the claims is required; this greatly reduces translation costs ($50-$70 per page for each language); and a shorter specification speeds up examination and litigation review – in order to maximize the accuracy of the translation, the specification should be written in the simplest and clearest language – rather than discussing the prior art, the foreign application should include a list of references (and let the examiner state his view of how they relate) – the specification should describe the invention in a manner reflecting the prior art, and may even refer to the claims ("the invention comprises the process defined in claim 1…") – the specification should not state that the invention has any "object," nor recite advantages or desired results, because these can be construed as limitations; rather, the applicant may talk around the invention, e.g., "we have discovered, in accordance with the present invention, that [result]" – similarly, foreign claims may not be directed to a feature shown or described in only some of the drawn or described embodiments; thus, features to be relied on for patentability should be discussed as generally applicable to all embodiments – however, foreign applications have no best-mode requirement, a reduced standard of enablement, and no requirement that every claimed feature must be shown in an illustration; so if the PCT application is not going to be converted into a U.S. application, much of this material can be excised – of course, non-metric measurements must be converted to metric units, but the original measurements can be included in parentheses
- Revising the U.S. independent claims for foreign filing: Foreign patents cannot have multiple independent claims that rely on different features for novelty (attempts to do so will draw a restriction requirement), so all independent claims except the most important one should be removed from the application – it may be possible to draft one independent claim that claims the features of each U.S. independent claim in the alternative – however, separate independent claims for the same novel purpose may exist, e.g., different statutory classes involved in the same process – also, independent claims can back-reference other claims for definitions, e.g., "apparatus as claims in any one of claims 1 to 6" – many foreign countries prefer or require Jepson-style independent claims that recite a "pre-characterizing clause," but the clause should describe the prior art according to the single most relevant prior art document; but the claim can be filed as normal and revised later, depending on which reference the examiner seems to find "most relevant" – foreign claim-drafting practice is influenced by some litigation factors: contributory infringement is not recognized in many foreign courts, so claims should be oriented for directly covering potential infringers in all foreign countries; also, since discovery is limited or nonexistent, infringement can only be proven by direct examination; also, foreign courts may not recognize or apply the doctrine of equivalents, so claims should reliably countenance literal infringement

- Revising the U.S. dependent claims for foreign filing: Most foreign patent offices require dependent claims to be patentably distinct from their parent claims, and many charge considerable fees for additional claims; accordingly, most foreign patents have only one or a few claims – however, multiply dependent claims are much more common in foreign applications (and do not incur large fee penalties as in the U.S.) – a good strategy is to file the PCT application with about twenty claims and narrow them for each national-phase filing (about 10 for the EPO filing, and three or four for the Japanese filing)
- Foreign practice differences: First, USPTO rules that qualify or disqualify references as prior art differ from the rules generally applied by most foreign offices (though most of them use substantially the same rules) – most notably, foreign offices require "absolute novelty": there is no grace period between a publication and the prior-art bar; every foreign application must be filed before the publication, or after the publication but with a valid priority claim to a U.S. application filed before the publication – however, there is no foreign on-sale bar if the invention is not disclosed as part of the sale – also, applications filed by the same applicant are not valid against the applicant in an obviousness rejection until the earlier application publishes

Chapter Sixteen: Reissue Patent Applications

- Overview: Many patents issue with errors ranging in magnitude from spelling to claims anticipated by a prior art reference – four processes are available for correcting errors: disclaimer of part of the tail end of the patent term (35 USC §253), certificates of correction for minor errors that do not require substantive consideration (35 USC §§254-255), reexamination proceedings (either *ex parte* or new *inter partes* practice) for considering newly-raised prior art (35 USC §§301-307), and reissue applications for materially defective patents (35 USC §251)
- Uses of reissue proceedings: A reissue patent can broaden unduly narrow claims (only within two years of issuance), narrow invalidly broad claims, correct claim ambiguity, add statutory classes, fix inventorship or priority errors, supplement the specification with information shown in the drawings (as originally filed), or supplement the specification with inherent but undisclosed properties of a chemical compound – however, reissue proceedings cannot recapture subject matter disclaimed during prosecution ("Recapture Doctrine" – see *In re Clement* (1997)) or correct fatal errors like non-enablement or failed disclosure of best mode
- Protection from a broadening reissue: Reissue is considered an equitable procedure, so it can be withheld where inequitable conduct has occurred, or where the rights of competitors or the public would be unfairly burdened (35 USC §252) – absolute intervening rights: competitors have a right to use subject matter disclosed but not claimed in a patent, and so the patent cannot be broadened after issue in order to sue for infringement; the competitors can be enjoined going forward, but must be allowed to sell their stock of products manufactured in good faith – also, a court may equitably grant a competitor limited immunity from infringement of a broadened reissue patent where they invested development costs and commenced business (in good faith) before the reissue; the CAFC approves

this doctrine and encourages heavy use (*Seattle Box C. v. Indus. Crating & Packing, Inc.* (1984))

- The reissue process: A patentee must show diligence in filing a patent application, but diligence is presumed if the patentee files within two years of issuance – the reissue patent is filed exactly like a utility patent application (specification, drawings, information disclosure statement, documentation of ownership) – in addition, the patentee must submit (a) a reissue oath according to 37 CFR §1.63, asserting a belief that the original patent is wholly or partly invalid due to claim breadth or specification errors (specific reasons must be set forth); and (b) an offer to surrender the original patent (37 CFR §1.117(8)(a)) – the original specification may be submitted, with changes made as per 37 CFR §1.173(b), but claims cannot be renumbered, and new claims are appended with the next highest claim number – drawings may also be resubmitted from the original patent, so long as there are "no changes whatsoever" in the reissue application; changes must be drawn in red, according to 37 CFR §1.121(b)(3) – notably, the reissue application will be accepted as "special" and will retain that status throughout prosecution
- Tactical considerations: Not all errors need to be corrected, and those that should may not be warranted by costs – also, sometimes the USPTO will invalidate a reissue application in light of new prior art, when the CAFC would not (*In re Am. Acad. Sci. Tech. Ctr.* (2004))