Landis on Mechanics of Patent Claim Drafting Robert C. Faber, Fifth Edition

Chapter One: Statutory Provisions – Some Basic Principles

- 35 USC §112: "The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention" this principle dates back to the Patent Act of 1836, and predominates the practice of patent prosecution this phrase includes two distinct requirements, but satisfying one usually satisfies the other the core purpose of this clause is to differentiate the patent from the prior art
- "Omnibus" claim: This claim style simply specifies "a device substantially as shown and described," or "any and all features of novelty prescribed, referred to, exemplified, or shown" this style used to be very common, and is still common in foreign patents, but is now considered non-statutory for failing to "particularly point out and distinctly claim" the invention
- Peripheral claiming: 35 USC §112 requires inventors to engage in "peripheral" claiming by delineating the periphery of the patent as viewed against the field of technology and prior art this is helpful for the public and competitors who wish to avoid the patent, but can be difficult for the patentee, as it requires some foresight about future inventions to mitigate this difficulty, the courts created the doctrine of equivalents to allow some degree of expansion of the metes and bounds to encompass competing inventions
- Statutory classes: 35 USC §101 sets forth four main classes of patentable inventions: "process," "machine," "manufacture," and "composition of matter" (as well as "combinations" and "improvements" thereof) nothing can be patented unless it can be characterized under one of these four concepts this statute is often invoked to reject patents for mathematical formulae, algorithms, printed matter, and articles of nature e.g., no element of a process can be a person (Cardiac Pacemakers, Inc. v. St. Jude Med., Inc. (2002): "third monitoring means for monitoring the ECG signal" was held to specify a human observer, and thus an unpatentable method) however, these classes are interpreted broadly, manmade organisms are patentable as compositions of matter (Diamond v. Chakrabarty), and applied software and business methods are patentable as processes (State Street Bank & Trust Co. v. Signature Financial Group, Inc. (1998))

Chapter Two: Claim Forms and Formats in General

- <u>Placement after specification:</u> 35 USC §112 requires the claims to conclude the specification this rule isn't fully enforced, but it is good form
- <u>Single sentence:</u> 35 USC §112 requires each claim to take the form of a single sentence, which unfortunately leads to very protracted sentences the claim block should begin, "I claim," or "The invention claimed is," or something similar; each

- claim should also begin with a capital letter and end with a period ("A pencil having a fastener at one end." *see Reckendorfer v. Faber* (1875)) verb forms should also match throughout the claim
- Numbering and order: In design and plant patents, only one claim is permitted; utility patents can and usually do have many claims patents with one claim should not include numbers, but multiple claims should be numbered consecutively MPEP §608.01(m): claims should be ordered with the broadest claim first, and similar claims should be grouped together (a patent claiming both a process and its product should group the claims to each concept); a horizontal line can be used to separate different groups of claims
- Numbering during prosecution: When a claim is canceled in prosecution, its
 number is not reused, and the others are not renumbered claims added during
 prosecution are appended to the claim set, and are given the next highest number
 when the patent issues, the USPTO renumbers all claims to produce a
 consecutive set if a continuation patent application is filed, the claims in the
 original patent should be logically renumbered
- <u>Preamble:</u> Every claim should have an introductory section called a "preamble" indicating the statutory class of the invention and describing it as a whole shorter preambles are preferred (*Karsten Mfg. Corp. v. Cleveland Golf Co.* (2001): "an improved correlated set of iron-type golf-clubs" preamble was construed to use "correlated" as a claim limitation)
- Preamble scope: The preamble should be consistent with the scope of the actual claim, and should be revised if the claim scope is modified –the title of the invention should be similar to the preambles of the claims, but can vary as needed, since the title cannot be read as a claim limitation an overly broad scope ("an apparatus comprising") is poor form it's important that the preamble match the invention described in the specification: if the specification calls for a bicycle, the claim should not specify "vehicle"; similarly, if the invention is useful on bicycles or motorcycles, the claim should not specify "bicycle"
- Preamble limitations: The preamble should not include unnecessary limitations; if a limitation is necessary for the claim to be patentable, it should be included in the body of the claim, perhaps in a "whereby" clause but if the limitation is needed to put the rest of the claim in proper and understandable context, it can be featured in the preamble composition of matter claims that describe a new and unnamed material may need to include several preamble limitations just to describe it, or may include it as a whereby clause ("a composition having density w and color x, comprising materials y and z"; "a composition comprising materials y and z, whereby the composition has density w and color x") preambles with additional nouns may make the transition ambiguous ("apparatus for shaking articles comprising..." do the following limitations apply to the apparatus or the articles?); this can be clarified by re-specifying the class ("apparatus for shaking articles, the apparatus comprising...")
- <u>Preambles in dependent claims:</u> A dependent claim implicitly, if not explicitly, includes the text of the parent claim it's incorrect to specify an invention in a dependent claim that is broader in any aspect than its parent claim (a claim to an "apparatus for shaking articles" should not be referenced by a dependent claim to

- an "apparatus for holding articles during shaking"; if each aspect is important, claim them with separate independent claims) more commonly, the dependent just recites the statutory class ("the apparatus of claim 1, further comprising...")
- <u>Jepson claim preamble</u>: A Jepson claim describes the prior art, before specifying an improvement to it Jepson claim preambles are usually quite long, and the descriptors of the prior art are always considered limitations and relevant to the scope of the claim, so accuracy is important
- <u>USPTO use of preamble:</u> The USPTO relies on the preamble to triage the application to an appropriate examining group, so crafting the claims with this goal in mind is helpful
- Preamble as claim limitation: Precedent is split as to whether preambles limit the claims the general rule is that the preamble is a limitation if it "breathes life and meaning into the claim" (MPEP §2111.02), and is not a limitation if it "simply states the intended use or purpose of the invention" (*C.R. Bard, Inc. v. M3 Sys., Inc.* (1998))
- Preambles found to be claim limitations: Invention "producing on a photoreceptor an image of generated shapes made up of dots" was held to be functionally interwoven with the claim body, and thus a limitation (*Pitney Bowes, Inc. v. Hewlett-Packard Co.* (1999)) also, detailed description in the preamble of the structure of a claim element used in a method process was found to be a limitation (*Eaton Corp. v. Rockwell Int'l Corp.* (2003)) where the preamble characterizes the invention as a method of "treating or preventing" a condition, and the claim body references "a human in need thereof," the preamble is functionally tied to the claim body and "breathes life and meaning" into it, thereby rendering it a limitation (*Jansen v. Rexall Sundown, Inc.* (2003)) similarly, if a claim recites a method of diagnosing a particular condition, it cannot be effectively used without this goal in mind and would be an "empty exercise," and thus is a limitation (*Griffin v. Bertina* (2002))
- Preambles found not to be claim limitations: Preamble recites a "communication system" but this term does not appear in the body of the claim, and is not a limitation (NTP, Inc. v. Research in Motion Ltd. (2002)) – similarly, "a method for reducing hematologic toxicity in a cancer patient" merely describes how the invention might be used, but the method can be infringed by application in other contexts; thus, "reducing" portion not a limitation (Bristol-Myers Squibb Co. v. Ben Venue Labs, Inc. (2001)); contrast with Griffin above, where a specific diagnostic purpose was required – where the preamble simply suggests using it in one context ("located at predesignated sites such as consumer stores"), but the method can be similarly utilized in other contexts, the claim is not a limitation (Cataloina Mktg. Int'l, Inc. v. Coolsavings.com, Inc. (2002)) – where the preamble describes features necessarily involved in an invention, but the claim does not depend on or mention those features, it is not a limitation (Schumer v. Laboratory Computer Systems, Inc. (2003)) – finally, if the claim body recites a "structurally complete invention" that does not need the preamble language for support, the preamble is not limiting (*Intirtool v. Texar Corp.* (2004))
- <u>CAFC guidelines for identifying limiting language:</u> In resolving this ambiguity of precedent, the CAFC specified five cases where preamble language is limiting:

Jepson claim preambles; claim body reliance on the preamble language for antecedent basis; preamble needed to understand elements in the claim body; specification emphasizing additional elements as important; and apparent use of the preamble to avoid prior art – examples of prior art avoidance: claim to "*E. coli* cells" modified to "*E. coli* cells of improved competence" during prosecution; CAFC held this as necessary to avoid prior art, and therefore limiting, even though the body of the claim was unchanged – similarly, addition of "rich in glucosinolates" considered limitation for avoiding prior art

- <u>Transition term:</u> The word between the preamble and the claim body materially affects the claim two most common transition terms: "comprising" and "consisting of" these terms may be used to describe sub-elements in a claim, and are similarly interpreted in that context
- Transition term "comprising": This term means "including the following elements but not excluding others"; this is an "open" transition term, allowing, e.g., a method claim to cover infringing methods that include additional steps synonyms: "including," "having," "containing," and even "wherein"; but these other terms may be construed as less open than "comprising" (*Lampi Corp. v. Am. Power Prods., Inc.* (2000)) if many of the elements "comprising" an invention share a common characteristic, a competing embodiment may infringe even though not all of the elements share that characteristic (*Texas Instruments, Inc. v. U.S. Int'l Trade Comm'n* (1993))
- "Consisting of": This term means "including the following elements, no more and no less" (MPEP §2111.03) synonyms: "composed of," "constituting," and "being" while presumptively closed, these terms may be open-ended if so described in the specification a composition "consisting of" certain elements may contain trace amounts of other non-functional elements, but no more than that however, a competing product may still infringe if it adds an element that is non-functional; e.g., a claim to a chemistry kit "consisting of" certain elements but not specifying a spatula encompasses a kit that does include the spatula, because the spatula is not a functional part of the invention (*Norian Corp. v. Stryker Corp.* (2004)) "consisting of" is always used for Markush groups
- "Consisting essentially of": This slightly broader version of "consisting of" allows the addition of elements that do not "affect the basic and novel characteristics of the invention" (MPEP §2111.03; *In re Garnero* (1969)) typically used for compositions of matter, but may also be used in methods synonym: "composed of" is sometimes interpreted with this scope other hybrids exist; e.g.: "consisting prevailingly but not essentially of" (U.S. Pat. No. 3,112,301)
- <u>Claim body:</u> The body of a claim recites the elements of the claim and describes how they cooperate structurally, physically, or functionally to form an operative invention elements that do not cooperate in some fashion are at best an "aggregate" and probably render the claim inappropriate the claim language should be technical, not laudatory or surplus (e.g. "an apparatus comprising an iron, thus to iron clothes more effectively than before": the latter clause should be deleted) where the invention is a single element (e.g., a pure composition), it is simply described; but no "means plus function" claim can consist of a single means or element

- Format and punctuation: Claim elements are usually specified as a list, separated by commas or semicolons old list style: all elements specified in a single-paragraph sentence; this is still preferred for claims with two elements modern style: multiple subparagraphs indented to offset elements (MPEP 608.01(m)) some patents feature an outline style, prefacing each claim element with (a), (b), (c), etc.; this is usually less readable than the subparagraph style, but may be helpful for claims that refer back to previous elements ("after step (c)")
- Dependent claims: A dependent claim includes the whole text and limitations of the parent claim on which it depends the "infringement test" of dependency: the dependent claim "shall not conceivably be infringed by anything which would not also infringe the basic claim" (MPEP §608.01(n)) a dependent claim cannot remove any limitation of the parent claim ("the device of claim 1 without element (x)"); this should be written as a new independent claim also, the dependent claim must add either new elements or further limitations to previously specified elements; of course, either addition renders the dependent claim narrower than its parent claim e.g., a composition patent may include a dependent claim that either adds an element not specified in the parent claim, or further describes (limits) an element featured in the parent claim the advantage of dependent claims is that they are easier to examine than a new independent claim, and if a claim is allowed, all claims that properly depend on it are also allowed without further examination (*Ex parte Ligh* (1967))
- Dependent claim structure: An invention may be independently claimed with a number of general-purpose elements, but may be optimally used with specifics this invention should be first claimed with a broad independent claim rather than making one dependent claim string with each narrowing one element, it would be better to create a number of dependent claims all depending on the independent claim and each narrowing one element also, a dependent claim should remain consistent with the preamble of the independent claim; if the invention has been so narrowed that the independent claim preamble is no longer encompassed by the claim, then a new preamble may be introduced ("a method of ____, as recited in claim 1, wherein..."), or the claim should be written as a new independent claim the latter option is particularly desirable where the narrowing limitation is a core feature of the preferred embodiment
- <u>Dependent claim preamble:</u> The preamble of a dependent claim should clarify the dependency ("the apparatus of claim 1, wherein..."), but dependency may be elsewhere specified ("a combination comprising (x), and the subcombination of claim 1, connected to (x)")
- Honeywell problem with dependent claims: A recent CAFC decision, Honeywell Int'l, Inc. v. Hamilton Sundstrand Corp. (2004), introduced the concept that when an independent claim is canceled during prosecution, and its dependent claim is rewritten in independent form to include all limitations from the independent claim, this counts as a narrowing claim amendment that creates a presumption of surrendered claim scope and bars the use of the doctrine of equivalents (citing Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co. (2002)) this decision was foreshadowed by Ranbaxy Pharmaceuticals, Inc. v. Apotex, Inc. (2003), which held that amending a claim to remove ambiguity did not operate as a Festo

surrender, but other amendments might – however, this use is only barred for elements that were at issue in the rejection and cancellation of the parent claim; the doctrine may still be used for elements not at issue in the parent claim and not altered by the dependent claim – this holding is odd because 35 USC §112 ¶4 imputes independent claim limitations into every dependent claim; thus, explicitly adding what is already implicitly part of the claim should not constitute "narrowing" – nevertheless, claim strategy may swing away from dependent claiming and prefer many independent claims – open questions: (1) is the doctrine of equivalents foreclosed for elements newly added by the dependent claim? (2) if one independent claim is canceled due to prior art pertaining to a particular element, is the doctrine of equivalents foreclosed for the same element and language in another claim?

- Number of claims: Patent law places no limitation on the number of independent claims in a patent application, or the number of claims that depend on an independent claim several dependent claims of identical wording may be included if they depend on substantively different independent claims (*Ex parte Primich* (1996)) the only legal limit is that the claims must not be "unduly multiplied" to claim essentially the same invention while filing and prosecution costs scale up with more claims, the costs may be trivial compared with the breadth of the ensuing patent
- <u>"Head claim":</u> This term describes an independent claim on which all other claims depend – this is not required or common in U.S. applications, but is more often used in other countries
- "Product by process" claim: A claim may depend on a parent claim in a different patent class this enables the "product by process" type of claim ("the product of the process of claim 1") conversely, the parent claim may recite a product, and the dependent claim may recite the process of making it in a particular manner see MPEP §608.01(n) and §2173.05(f) for more examples in both cases, the dependent claim must include all limitations of the parent claim, and it must pass the infringement test (e.g., infringement of the product claim must be impossible without infringing the parent process claim); thus, a product claim does not properly depend on a process claim if it can be made by other means also, a dependent claim that simply claims any method of making the product of a parent claim is unallowable, in part because it is not fully enabled however, if the separate inventions are sufficiently distinct, the examiner might issue a restriction requirement for each invention
- Dependent claim grouping: MPEP §608.01(n): "A claim which depends from a dependent claim should not be separated therefrom by any claim which does not also depend from said 'dependent' claim" thus, dependent claim ordering is a depth-first process while not required, it is logical and encouraged to follow this ordering for independent claims as well (place all claims that depend on an independent claim before the next independent claim)
- Rewriting a dependent claim as an independent claim: A dependent claim should not be rewritten by mechanically adding every limitation in every parent claim up to the independent claim this adds many unnecessary limitations rather, the spirit of the imputed limitations should be added, and needless limitations should

- be skipped (e.g., "An apparatus comprising a first element, wherein the first element comprises a mechanical fastener, wherein the mechanical fastener is a staple")
- <u>Independent claim design</u>: Independent claims should recite the invention as broadly and with as few limitations as possible of course, the independent claim should be broader and less limited than any claim that depends on it if the invention has several novel features, several objectives, or several structural designs that achieve the same purpose, then multiple independent claims should be written to cover each aspect however, independent claims are more difficult to prosecute and more expensive, so they should not be used to cover different embodiments that could be described by one broader claim as noted above, in light of *Honeywell*, it may be preferable to write many independent claims than sets of independent/dependent claims
- Multiple dependent claims: Rule 75(c) and MPEP §608.01(n) define a multiple dependent claim as one that refers to two or more previous claims in the alternative e.g.: "the apparatus of claim 1 or claim 2, further comprising..." must be in the alternative ("an apparatus according to claims 1-3" is unallowable), must specifically point to previous claims ("an apparatus of any of the previous claims" is unallowable), and must reference prior claims for the same reason ("an apparatus of claims 1 or 2, made by a process of claims 3 or 4" is an unallowable "doubly multiple dependent" claim) a multiple dependent claim may form the basis for a dependent claim, but not for another multiple dependent claim
- Claim filing fees: The basic filing fee for a patent application covers 20 claims, including three independent claims charges are added for each claim over 20, for each independent claim over the third one, and for multiple dependent claims (MPEP §608.01(n): "a multiple dependent claim is considered to be that number of dependent claims to which it refers; any proper claim dependent directly or indirectly from a multiple dependent claim is also considered as the number of dependent claims as referred to in the multiple dependent claim from which it depends") also, a one-time fee is charged if the application features a multiple dependent claim (either at filing or if added via amendment) the additional fees discourage the use of multiple dependent claims
- Festo impact on claim amendments: Infringement of a patent requires proof that the accused product or process is covered by one or more claims, either literally or by the doctrine of equivalents the CAFC ruled in Festo Corp. v Shoketsu Kinzoku Kogyo Kabushiki Co. (2000) that any claim amendment that narrows the scope of a claim element for a purpose related to patentability (§112, §102, or §103) bars the later application of the doctrine of equivalents for that claim element the Supreme Ct modified this ruling by stating that this only creates a rebuttable presumption of inapplicability, and suggested scenarios where the doctrine may still apply ("the equivalent may have been unforeseeable at the time of the application; the rationale underlying the amendment may bear no more than a tangential relationship to the equivalent in question") on remand, the CAFC created a three-part test: (1) did the amendment narrow the literal scope of the claim element? (2) was the amendment related to patentability? (3) what scope remains for the narrowed patent, outside that surrendered by amendment? the

- CAFC also created a rebuttable presumption for the second point subsequent decisions (*Honeywell* and *Apotex*) have further applied *Festo* to dependent claims rewritten in independent form after the parent claim is cancelled (see above) however, *Festo* does not apply to amendments made to broaden a claim, or to clarify the claim language
- <u>Festo in practice</u>: The best way to avoid *Festo* is to never amend a claim, but this is often impossible thus, practitioners face a dilemma: a broad claim would be very valuable if allowed, but may damage the scope of the patent if it must be amended; the current trend continues to favor broad claims

Chapter Three: Apparatus or Machine Claims

- Overview: "Apparatus" includes machines, devices, electrical circuits, computerrelated items, and hydraulics – essentially, an apparatus is any item containing mechanical and/or electrical parts that cooperate for a useful purpose
- Example apparatus claim:

Apparatus for shaking articles, which comprises:

- (a) a container for the articles;
- (b) a base;
- (c) a plurality of parallel legs, each leg connected pivotally at one end to the container and the other end to the base to support the container for oscillating movement with respect to the base; and
- (d) means for oscillating the container on the legs to shake the articles.
- Preamble class: The preamble shown above is typical for apparatus patents: recites a statutory class ("apparatus", or synonyms "machine", "device", etc.) and a very brief purpose for context if the device has a generic name ("circuit", "carburetor", "lawn sprinkler", etc.), it's best to use that instead of "apparatus" apparatuses that achieve several purposes may be claimed: "In combination, an A, a B, and a C"; this might also be appropriate when a dependent claim adds a component or function to an element in the parent claim ("inc combination, the means for oscillating a container of claim 2, and a container…")
- Preamble contextual breadth: The breadth of the context should match the breadth of the invention: a general-purpose tool claim might begin: "apparatus for performing a specific act or operation on a particular article or workpiece"; a more specialized tool might begin: "apparatus for detecting discontinuities in the insulation of an insulated wire" the context can alternately be included in a "whereby" clause
- <u>Preamble as limitation:</u> As noted in Chapter 2, preambles are sometimes considered claim limitations however, they are always considered relevant for patentability (MPEP §2111.02) by contrast, "whereby" clauses are always construed as limitations
- Elements of apparatus claims: An "element" is a structural part of the apparatus a "workpiece" or "article" is an item on which an apparatus works, and usually modifies, but is not a part of the actual apparatus
- <u>"Inferential" claiming:</u> One general rule is that each element should refer only to elements previously introduced an element should not be "inferentially" introduced in a claim featuring another element as its subject (e.g., "a motor

driving a cam shaft") – thus, if elements A and B are attached, claiming "element A attached to element B, and element B" is wrong; claiming "element A, and element B attached to element A" is correct – exception: the workpiece is not introduced as an element in its own subparagraph, but is merely referenced at the earliest convenience within another claim element – a somewhat related rule is that active verbs should be avoided: not "element A is connected to element B", which reads as instructions for building the apparatus, but "element A connected to element B", which reads as a description of the complete apparatus

- Number of elements: The broadest independent claims should feature the minimum number of elements to support patentability in the example claim above, the container, base, legs, and oscillating means are all necessary; a more limited claim would also include a motor, cam, and cam follower linkage it is helpful to consider what elements an infringing device must have however, claiming too few elements renders the claim incomplete and inoperative
- "Workpiece" or "environment" element: Many apparatuses work on a particular item, or interact with the environment in which it is used these include fuel on which a claimed engine operates, and celestial bodies that a claimed telescope is intended to present for observation such an element is not recited as a proper element in its own subparagraph, but must be mentioned to make the claims operative it might be first mentioned in the preamble ("a juicer for squeezing citrus fruit, comprising..."), or might be left out if the device is intended for broader use ("a juicer comprising...") it is helpful to imagine what the patentee (and competitors) will sell as the invention, and what might be included separately (e.g., replaceable parts); this may be the difference between suing a competitor as a direct infringer, and as merely a contributory infringer (if he sells the actual invention, but omits workpiece/replacement parts that are included as claim elements)
- Negative limitations: MPEP §2173.05(i): "there is nothing inherently ambiguous or uncertain about a negative limitation"; *In re Duva* (1967) approved such use a negative limitation may be written as "a halogen other than fluorine," or an element described as "noncircular" or "colorless" however, such stark language may preclude the doctrine of equivalents, and it may be better to use phrases like "not in excess of 10% halide" *Duva* involved a combination of A, B, and C that was disabled by presence of D, and was thus claimed like "comprising A+B+C and absent sufficient D to disable the combination"
- Support in specification and drawings: All terms and phrases used in the claims must have "clear support or antecedent basis in the description so that the meaning of the terms in the claims may be ascertainable by reference to the description" (MPEP §2173.05(i)) of course, this also applies to negative limitations unsupported claim terms are rejected as "indefinite" under 35 USC §112; the best way to avoid this result is to include the claims almost verbatim in the specification however, elements claimed under 35 USC §112 ¶6 can be listed more broadly in the claims; e.g., the specification refers to a "hammer," but the claim describes "means for hammering"
- <u>Drawings:</u> A drawing should be filed with an application if necessary to understand it (Rule 81(a)) the drawings must show every feature specified in the

- claims (Rule 83(a)), but even where this is the case, the specification should also describe them, and the claims, specification, and drawings should be consistent
- Naming elements: Each element should be given a specific name in the claim, and should be consistently referenced by that name throughout the claims and specification – these names should be affixed early in the patent drafting process, which helps with identifying critical claim elements – the exact term chosen is not important, as long as it fairly captures the function of the element, either in its ordinary usage or as explicitly defined in the specification – however, the name should not be chosen too narrowly; a "fastening element" is broader than "screw" or "nail" – because of the doctrine of claim differentiation, if one claim element is named in a broad claim and described in more detail in a dependent claim, the independent claim element will be more broadly interpreted – also, two similar elements should be given distinct names, like "holding means" and "support means"; where this isn't possible, "first holding means" and "second holding means" can be used – however, the "first" and "second" adjectives merely differentiate different elements: they do not imply any other feature, e.g., temporal ordering of the elements (3M Innovative Properties Co. v. Avery Dennison Corp. (2003)) – consistency is important, particularly within a chain of dependency (don't use "structural member" in an independent claim, and reference it as "support member" in a dependent claim) – adjectives can be dropped in later references if the shortened form is unambiguous ("connecting appendage" may later be referenced "appendage," presuming there is no other "appendage" element); however, the adjective can never change (e.g., to "tying appendage") (Ex parte Oetiker (1992))
- Intrinsic evidence: Where a term is not explicitly defined, it is given its ordinary meaning, relying on any context found in the specification, and possibly the prosecution history – if ambiguity remains, the parties may suggest dictionaries, encyclopedias, and learned treatises as intrinsic evidence (Texas Digital Systems, Inc. v. Telegenic, Inc. (2002)) – the previous view was that these texts were secondary sources of intrinsic evidence, and were secondary to the apparent meaning of the specification (Combined Systems, Inc. v. Defense Technology Corporation of America (2003)); however, Texas Digital and other recent cases (W.E. Hall Co. v. Atlanta Corrugating LLC (2004)) put treatises on equal footing with the specification, and encourage their use except where they contradict the clear meaning of the terms used in the specification (Int'l Rectifier Corp. v. IXYS Corp. (2004)) – however, the text selected must be appropriate for the field of art; a general-purpose text shouldn't be referenced for defining terms with special meaning in the art (Vanderlande Industries Nederland B.V. v. Int'l Trade Comm'n (2004)) – Appendix D of this treatise features many definitions common in mechanical patents
- Express definitions: A patent applicant "may be his own lexicographer" (MPEP §2173.01), but cannot define a term with a meaning "repugnant" to its usual meaning (MPEP §2173.05(b)) the applicant should clearly state the definition in the specification ("As used in this description and in the appended claims, the word X means Y.")

- <u>Claiming embodiments</u>: Each embodiment that is disclosed must be encompassed in one or more claims failing to do so may cause the embodiment to be dedicated to the public (*J&J Associates, Inc. v. R.E. Service Co.* (2002); *PSC Computer Prod., Inc. v. Foxconn Int'l, Inc.* (2004)) of course, the doctrine is always available to cover embodiments that were not disclosed, but that may be equivalent to a claim
- Singular and plural elements: An element can be claimed as a plurality ("three or more springs"; "a plurality of rods"; "at least one arm") – the minimum number needed for proper functioning should be specified; claiming "a pair" will not cover a device featuring one such item – by contrast, claiming "one" or "a" item may or may not include a plurality of such items (contrast *Abtox*, *Inc. v. Exitron* Corp. (1997) and Elkay Mfg. Co. v. Ebco Mfg. Co. (1999)) – an upper bound to a plurality need not be specified, even in the case of "a pair," when using "comprising" to encompass additional elements; however, "at least" is still recommended for clarity; but where the claim must be limited to an upper bound, language like "at most three" is acceptable – also, it's important to clarify which element a numeric phrase qualifies: "at least one of X, Y, and Z" has been construed to mean any combination of single items X, Y, and Z, but not multiple X's (Superguide Corp. v. Direct TV Enterprises, Inc. (2004)) – however, two ranges should not be included ("20-40mm, and optimally 25-35mm"); similarly, a claim should not feature more than one element with an unbound upper percentage range ("at least 20% X, and at least 20% Y"), since this raises the potential of more than 100% composition of these elements
- <u>Double inclusion of elements:</u> This occurs when the same element is mentioned by two different names, and this always renders the claim indefinite this can occur by incorrectly referencing an element in a parent claim as a new element in a dependent claim, rather than referencing and further defining it (e.g., "an oscillating means" dependently clarified as "claim 1, further comprising a motor" is incorrect; "wherein the oscillating means comprises a motor" is correct)
- Reference numerals in claims: A claim may refer to elements shown in drawings by numerals, so long as the numerals are enclosed by parentheses, and their use has no effect on the scope of the claim (MPEP §2173.05(s)) this is rare in the U.S., but more common in other countries
- Antecedent basis: Every element should be introduced by an article, usually "a" or "an", except when introduced as a plurality or as "means" every subsequent reference to a previously-introduced element should be prefaced "the" or "said" (some practitioners use "said" to refer to elements, and "the" for other features) as noted above, adjectives may be dropped in subsequent references only if the reference is unambiguous: "supporting member" can be later referenced as "said member," but if the invention also includes an "oscillating member", subsequent references should be "said supporting member" and "said oscillating member" even more importantly, do not add limiting adjectives in subsequent references ("said horizontally supporting member"); this "indirect claiming" style is ambiguous where necessary, a claim may rely on itself for antecedent basis (e.g.: "a handle connected to the gear, the handle being axially aligned with the support member")

- <u>Inherent components:</u> MPEP §2173.05(e) indicates that common nouns have properties that need not be explicitly called out as elements a sphere always has an outer surface, so "the outer surface of said sphere" is an appropriate reference to a claim previously reciting "a sphere" however, complete clarity may require calling out these features as elements anyway
- Relative terminology: Relative adverbs and adjectives are indefinite unless qualified with more exacting language *Norton Co. v. Bendix Corp.* (1971): "closely spaced" and "substantial distance" both held to be indefinite, since a competitor could not determine whether his device infringed other vague terms include "more" and "less", " "rich in glucosinates", "high", and "effective amount" but if used in a way that more definitively limits their interpretation, all of these words are acceptable: "more than the minimum", "shorter than the preset value" used in this way, "about", "essentially", "similar", "substantially", and "relatively thicker" have all been upheld in litigation
- Alternative and hedged expressions: "Either" and "or" are permissible, unless they cause ambiguity of scope "made entirely or in part of" and "iron, steel, or any other magnetic material" are both OK sets of alternatives are often treated as Markush groupings, and so must be carefully specified also, the element being defined should not be specified as one of alternatives: "a spring or a weight for balancing..." improperly claims different items as a claim element (and would be more difficult to reference later) instead, the applicant should use terminology generic to both types ("balancing means") this particular rejection basis might be reversed: *In re Wolfrum & Gold* (1973) allowed a claim featuring a Markush group as the subject; but for now, alternative claiming of elements is generally rejected for the same reasons, "hedged" expressions are rejected: "a drive means, such as a motor, for..." attempts to recite both an independent claim and a narrower dependent claim in one claim; naturally, these should be specified as two claims however, "optionally" is permissible ("containing A, B, and optionally C"), unless the range of alternatives is infinite or indefinite
- Parts or features of elements: Where relevant to functionality, the features of an element (the size, shape, geometry, construction material, constituent parts, apertures, orientation, etc.) should be mentioned as noted above, such features should not be described relatively ("thick"), but with reference to something else ("thicker than element X") ordinarily, these features should be described with or near the clause introducing the element, even if the purpose of the quality is not yet apparent ("a disc of resilient material having a peripheral groove", "a level having a forked end and a rounded end") inherent features need not be expressly claimed ("a fork having tines"), but it's good form to call them out if they are important to the structure where the cooperation of elements is an important claim limitation, the cooperation should be stated as soon as all of the elements have been introduced
- <u>Claiming empty spaces:</u> Past practice shied away from reciting an empty space as a claim element, e.g., "hole", "groove", "aperture", "recess", "slot", or "chamber"; instead, practitioners claimed them as features of a claim element ("a lever having a groove") however, this restriction has not been consistently enforced, though a few examiners still issue rejections for such attempts

- Words of approximation: In order to avoid mathematical rigidity of magnitude terms, many practitioners soften them with approximation terms like "substantially", "about", "generally", "approximately", "almost", and "essentially" the CAFC has expressly approved "substantially" and defined it as "largely but not wholly" (*Ecolab, Inc. v. Envirochem, Inc.* (2001)) most of these terms are OK if their borders are described in the specification approximation terms ("of the type", "or the like", "relatively", "superior") are indefinite unless clearly supported in the specification the doctrine of equivalents was created to deal with just such situations, but the practitioner should not rely on its use, which is unpredictable rather, where allowable, approximation terms are encouraged, as they convert equivalent infringement to literal infringement ("pH 6" does not literally include "pH 5.8", but "about pH 6" does) even range elements can be softened with an approximation word ("substantially at least 6 inches") the specification should support all approximation terms, e.g., with a statement describing just how "approximate" a mixture should be to pH 6
- Order of elements: Any logical ordering of presented elements is permissible "functional" ordering describes the invention as an assembly-line of elements that work on a workpiece "structural" ordering describes the invention from the base, or the power source, to the elements that rely on it in order
- Tying the elements together: As noted, every element in an apparatus must be connected to at least one other element in the apparatus to constitute part of the whole failure to connect an element to anything prompts an indefiniteness rejection, often characterizing the claim as "a mere catalog of elements" or "an aggregation" if an element or element feature is truly not connected to anything else, it might be omitted one conceptual tool for determining which elements are needed is to draw a "stick" diagram, showing each part of the invention and conceptually connecting it to the others an exception to this rule is *In re Venezia* (1976), which allowed a claim to a kit of parts that do not actually cooperate
- <u>Structural connection:</u> A structural connection involves a mechanical relationship between elements a "means" clause might inherently include a connection with another element ("means for oscillating said container" inherently requires a structural connection to the container) often the actual means of connection is unimportant, and is generically stated as "connected" or "mounted on" (instead of, e.g., "bolted to" or "stapled to")
- Functional or operational expressions: A functional limitation restricts an element by its function within the apparatus, rather than its shape and makeup typical language: "providing" (a stated physical relationship in operation), "creating" (physical property), "such that" (functional relationship is achieved), "whereby" (an effect), and "and thus" (result); others include "so that", "for", and "in order to" a functional expression can be used in place of or in addition to a structural connection to state not just how some elements cooperate but why e.g.: oscillation means "connected to the container" specifies the physical link, but "for inducing oscillating movement of the container" specifies the functional relationship where used poorly, functional expressions render the claim indefinite; where used well, they more adeptly describe the invention, and claim it with greater breadth functional statements that describe movements, actions,

- and results are almost always permissible, but vague statements like "adapted to" are indefinite of course, "means for" terms are given special meaning under $\$112\,\6
- Overly broad functional statements: Some practitioners attempt to use functional language to claim a result or quality rather than a functional limitation – e.g., "a woolen cloth having a tendency to wear rough rather than smooth", which fails to "particularly point out and distinctly claim" the material – "the subject of a patent is the device or mechanical means by which the desired result is to be secured" (Knapp v. Morss (1893)) – similarly invalid are "the use of the motive power of the electric or galvanic current for making or printing intelligible characters. letters, or signs at any distance" (O'Reilly v. Morse (1853)), "a process for using monoclonal antibodies of claim 4 to isolate and purify interferon" (Ex parte Erlich (1967)), and "a liquefiable substance having a liquefication temperature from about 40°C to about 300°C and being compatible with the ingredient in the powdered detergent composition" (Ex parte Slub (1967)) – however, no clear test of overbreadth has been offered, and this is a frequent source of litigation (In re Echerd & Watters (1973): "having sufficient flexibility and wet strength to permit..." and "having sufficient adhesive characteristics to firmly bond..." pertaining to features that lacked novel structure but had novel function – the CAFC reversed the USPTO's rejection) – broadest allowed functional claim: "said plurality of lines *providing* a radial separation between panels upon deployment, creating a region of high porosity between the panels such that the critical velocity is less than (...) whereby said parachute will open and thus decelerate"; this claim style was approved by the USPTO (but rejected on prior art grounds) (In re Swinehart & Sfiligoj (1971))
- "Whereby": This clause is used to describe a function, operation, or result that necessarily follows from the recited structure or method these clauses are always relevant to the structure or method, but should not be intentionally used to add a limitation; instead, the limitation should be built into the claim body i.e., the parts should describe their own connections, and the "where prior art element is by" clause should be used to clarify the objective that they achieve correct: "a container for the articles, having apertured walls, the apertures of which are smaller in size than the articles to be shaken, whereby the articles are retained in the container as they are shaken"; incorrect: "an apertured container for the articles whereby the articles are retained in the container as they are shaken"
- <u>Location of functional clauses:</u> These should be either used at the end of a claim element description to describe the function it achieves, or at the end of a claim to describe the function that the overall invention achieves
- "Means" or "step" clauses: 35 USC §112 ¶6: "An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claims shall be construed to cover the corresponding structure, material, or acts described by the specification and equivalents thereof" this clause has the effects of including all equivalents for the claim element known at the time of the invention, but excluding all equivalents developed after the time of invention claims not written in this style "are not necessary limited to that disclosed in the

specification, but rather are defined by the language of the claims"; these are given the plain meaning of the words used – the USPTO used to hold that meansplus-function style could be invoked not just by "means for" or "step for", but by any style that clearly shows an intent to claim an element by the function it performs – now, §112 ¶6 is only invoked by (1) use of "means for" or "step for", (2) functional language following the clause, and (3) the absence of specified structure or material to accomplish the function (this precedent only controls the USPTO, not necessarily the CAFC; but see AMP, Inc. v. Fujitsu Microelectronics, *Inc.* (1994)) – if the means-plus-function language does not properly specify a function, it is rejected as indefinite – "for" is not necessarily required (Unidynamics Corp. v. Automatic Prods. Int'l Ltd. (1998): "spring means tending to keep the door closed" sufficient to trigger §112 ¶6; Signtech USA Ltd. v. Vutek, *Inc.* (1999): "ink delivery means" also sufficient) – structure may be specified without barring §112 ¶6 interpretation if it merely "enables" the claimed function, but not if the structure "performs" the function (Medtronic, Inc. v. Advanced Cardiovascular Sys., Inc. (2001)); on the other hand, functional language can be added to supplement a clear structural definition without triggering §112 ¶6 interpretation (British Telecommunications PLC v. Prodigy Communications Corp. (2002)) – even using a technical term that implies a specific structural in the art will bar §112 ¶6 interpretation (Greenberg v. Ethicon Endo-Surgery, Inc. (1996): "detent mechanism" had a structural connotation sufficient to preclude §112 ¶6; contrast CCS Fitness, Inc. v. Brunswick Corp. (2002), where "lever moving element" was not sufficiently structural, and would not bar §112 ¶6)

- Means-plus-function interpretation: The means-plus-function limitation can cover an infringing device element if the infringing element (1) identically performs the function specified in the means-plus-function claim, and (2) has the identical structure as the element specified in the specification or an equivalent thereof the USPTO used to construe these clauses by finding any comparable structure in the prior art, presuming it qualified as an equivalent, and shifting the burden to the applicant to show that it wasn't; the CAFC instructed the USPTO instead to read the means-plus-function limitation in light of the specification for structural information and equivalent analysis this isn't construed as importing a limitation into the claims from the specification, but merely reading the claim language in light of the specification (Carroll Touch, Inc. v. Electro Mech. Sys., Inc. (1993)); nevertheless, it has this effect
- Means-plus-function drafting: Given the different interpretations of §112 ¶6 and non-§112 ¶6, it's good practice to include two independent claims, or one §112 ¶6 independent claim and a dependent claim "wherein the means for A comprises B" also, the specification should recite several examples of elements (either new components, or parts of another component) that could be used as the claimed means it's very good practice to include one element that is both broad and well-known in the art, e.g., stating that a means could be a "microprocessor" (e.g., a flowchart showing a black box labeled "microprocessor" for the means) this might be held indefinite, so alternatively suggesting more specific means is also recommended attention should be paid to the "single means rule," barring the use of means-plus-function language to specify an invention as a single means

- ("apparatus for shaking articles in a container, which comprises: means for oscillating the container to shake the articles"; see *In re Hyatt* (1983)); this may arise as a problem in a Jepson-style claim, where the improvement consists of a single novel component claimed in means-plus-function form: this is probably okay, but not necessarily a means clause may include another means clause (U.S. Pat. No. 1,971,193: "means for causing oscillations... said means including means for producing a magnetic field")
- Means-plus-function in prosecution: In formulating a prior art rejection based on an equivalent, the patent examiner bears the burden of proving equivalency by showing that (a) the prior art element performs the same function as the meansplus-function element, and (b) the specification does not provide a structural definition of equivalents that excludes the prior art element – the examiner must then prove anticipation or obviousness under §102 and §103 – the applicant may refute the presumption of equivalency – according to the Interim Supplemental Examination Guidelines for Determining the Applicability of 35 USC §112 ¶6 (1999), the examiner must show that the prior art element qualifies as an equivalent – if the applicant suggested the nature of equivalents in the specification, the examiner must prove that the prior art element qualifies; the applicant need not have described equivalent structure in detail in order to trigger this burden – but, if the applicant did not suggest any equivalents, the burden falls on the applicant to prove non-equivalency – tests of equivalency: (1) the prior art elements perform the same function in the same way to attain the same result; (2) the prior art element has the same structure that operates in the same way to produce the same result; (3) one of ordinary skill in the art would consider the prior art element interchangeable with suggested equivalents; (4) the prior art element is insubstantially different from a suggested equivalent
- <u>Step-plus-function:</u> All of the same rules apply to claiming a step not by how it is performed, but by what it accomplishes this is different from a preamble statement of purpose, or a whereby clause describing the end result as with means-plus-function, step-plus-function claiming should clearly be invoked by use of the term "step for" followed by functional language, without the "structural" description of the specific acts performed

Chapter Four: Method or Process Claims

• Overview: Process claims are usually easier to write than apparatus claims, because they have fewer elements, less structural glue, and less complexity – process claims often look like recipes – "method" and "process" are synonyms, according to 35 USC §100(b) – most general rules apply to methods: claims may be of variable breadth to inventions in any art, etc. – the "elements" of a method claim are actions, usually those that manipulate or transform an article or workpiece; also, diagrams are less often included than in apparatuses – the claim may consist of a single action (*Ex parte Kelly & Ford* (1967)) – a patentable process may be a conventional process working on a novel material, working on a material known but not previously used in such a method, or making a known material by a novel method; however, merely using a novel material or producing a novel material is not *by itself* sufficient (*In re Durden* (1985)) – one exception:

- Public Law 104-208 (1996) denies enforcement of patents for medical or surgical methods against medical practitioners, as long as the method does not involve a patented invention
- Elements of method claims: Each element of a method claim is usually a verb phrased as a gerund ("reciprocating the guide, impressing a signal, separating the components) a purpose may be included, e.g., "distilling the aqueous solution to separate the alcohol therefrom" in this case, an examiner may ask for a revision to the "more positive" phrase of "separating by distillation"; this is not necessarily needed: these forms are identical in function, and in such cases the patentee's preference should be heeded (*Ex parte Lewin* (1966)), and "distilling" may be construed as narrower than "separating" as the claimed step, thereby avoiding prior art the claim usually begins with a preamble, which should read like: "method of performing a specified act on a particular article, the method comprising:" a claim element can be in the "step-plus-function" form, according to 35 USC §112 ¶6, and all of the same rules apply as for apparatus functional claiming in fact, well-written step-plus-function claims can be converted to means-plus-function claims by replacing "method" with "apparatus" and prepending "means for" to each element, and vice versa
- Order of steps: The elements of a method claim are usually recited in temporal sequence where temporal ordering is intended, it is wise to make this express (describe step two as occurring after step one, or phrase the method "comprising the following steps in the order named") if steps are simultaneously performed, but one modifies another, the modified step should precede the modifying step if the ordering is unstated, the claim covers the steps in any order, including simultaneous steps (Altiris, Inc. v. Symantec Corp. (2003))
- Obvious method using novel starting material or producing unobvious product:

 The patentability of such methods was affirmed in *In re Ochiai* (1995), in which the CAFC held that the USPTO had improperly construed *In re Durden* to presume such methods *per se* obvious; the CAFC held that if the starting material is truly novel, and not just slightly different from previously known starting materials, a known process applied to the novel material could be patented, because the "subject matter as a whole" (including the novel starting product) was not obvious to one of ordinary skill in the art simultaneous with this decision, Congress passed 35 USC §103(b), expressly authorizing patents for obvious biotechnology processes that use or create novel biotechnology products
- Claims to methods as functions of novel apparatuses: Old principle: the process carried out by a novel machine is only patentable if it embodies its own novelty if "the disclosed machine will inherently carry out the steps of the process set forth in the process claims regardless of whether an apparatus claim is allowed, [and] can[not] be carried out by some machine which is not the functional equivalent, or by hand," then it was not patentable new rule: MPEP 2173.05(v): "process or method claims are not subject to rejection solely on the ground that they define the inherent function of a disclosed machine or apparatus" (following *In re Tarczy-Hornoch* (1968))
- <u>Apparatus limitations:</u> Often a step of a method claim will involve an apparatus, much like an apparatus claim specifying an action as an element; of course, the

apparatus must somehow "cooperate" in the method, not just be aggregated with it – however, this practice is discouraged, because the apparatus limitation may unduly limit the process claim (by using an alternative device or manual execution) – more importantly, a method claim cannot be based solely on the structure of an apparatus (*Ex parte Dammers* (1961)) – thus, an apparatus should only be included where the method specifically requires its manipulation as a step – on the other hand, compositions and chemicals are often included in method claims as products, starting materials, or transformative agents (*In re Kuehl* (1973): patent for using a new catalyst in a known method of cracking gasoline) – similarly, a dependent claim should not solely add an apparatus, but it may add a step involving an apparatus ("wherein the step of rotating the barrel includes mounting the barrel on a turntable")

- Chemical processes: "A process for treating a surface of a polyethylene article to increase its receptivity to printing ink, which comprises: exposing the surface of the article to a saturated solution of sodium dichromate in acid." (notice this claim is to a single-step method, which is fine) this could be dependently refined as "wherein the acid is sulfuric acid") Markush grouping can be used to specify different classes of materials in a step, specifying the use of "one or more of" the groups as noted above, *In re Ochiai* permits patents for the use of a novel and unobvious starting material in a known process, or the production of a novel and unobvious product by a known process *Ochiai* was preceded by *In re Kuehl* (1973), in which a new zeolite compound was suggested for use in a "notoriously old" chemical cracking process commonly using known zeolites, because the selection of the novel zeolite would have been unobvious
- <u>Electrical methods:</u> Nothing special here; the only difference is that electrical steps are specified instead of mechanical ones
- Computer program or software-related methods: These inventions can be claimed wither as a series of means comprising an apparatus, or as a number of steps comprising a method the USPTO used to utilize specific tests for patentability of software (e.g., the Freeman-Walter-Abele test: (1) does the claim appropraiate an algorithm? if so, (2) does the algorithm have any physical characteristic?), but all such tests and requirements were expressly abandoned by *State Street Bank & Trust Co. v. Signature Fin. Group, Inc.* (1998)), which held algorithms patentable as long as they solve a real problem algorithms that simply manipulate abstract numbers are unpatentable as a non-statutory "principle, law of nature, idea, or mathematical expression of scientific truth" (*Gottschalk v. Benson* (1972)) the USPTO issued guidelines in 1995 for examining "computer-implemented inventions," now codified (and broadened) by MPEP §2106, which instruct the examiner to correlate each claim element to a relevant component in the specification
- Claims for computer-implemented inventions: An algorithm may be claimed as a novel machine, comprising a general-purpose computer in which is embedded the novel algorithm it may also be claimed as a novel article of manufacture, comprising computer-readable media containing the algorithm it may most directly be claimed as a process; prior to *State Street Bank*, at least one physical element was necessary, but this is no longer true nonstatutory claims include (1)

- compilations of data not embedded on a physical element, (2) machine-readable media containing an artistic representation, (3) a "data structure" that does not involve a physical element, (4) a process that solely manipulates abstract ideas or concepts of course, any such claim must be written in English, not specified in any computer language, unless there's no other way to claim it the invention may be claimed under 35 USC §112 ¶6 by specifying it as a series of "means for" or "steps for" achieving different transformations
- Business methods: State Street Bank & Trust Co. v. Signature Fin. Group, Inc. (1998) sanctioned patents for any business method "limited a practical application of an abstract idea or mathematical expression in the technical arts"; as with all software patents, this need not involve any physical component – this decision was clarified in AT&T Corp. v. Excel Communications, Inc. (1999) as requiring a "useful, concrete, and tangible result," but not a physical act – most such patents are classified under 705, which includes algorithms pertaining to insurance, securities trading, health care management, reservation systems, postage metering systems, auction systems, and business cryptography – business methods can also be claimed as apparatuses, particularly where they accept input and transform it into output – patents exist for the process of drafting a patent application using a computer to perform at least one step (U.S. Pat. No. 6,049,811), claiming both a process and a machine, and also the method of preparing an income tax return – much outcry exists over business patents, including one high-profile case (Amazon.com's "one-click" system of ordering goods, U.S. Pat. No. 5,960,411) – a business method can even be patented outside the use of a computer, provided it proposes a novel and nonobvious set of steps ("a method for performing a financial transaction comprising..." followed by many steps not involving a computer; this could also be claimed as an apparatus, simply specifying means for performing each step)

Chapter Five: Article of Manufacture Claims

- Overview: An article of manufacture is essentially the same as an apparatus, consisting of a combination of elements named and tied together into a mechanism most of the rules for apparatuses apply however, *In re Venezia* allows article of manfacture patents for a kit of unassembled parts components may be distinguished from the prior art by shape, arrangement of parts, construction material, or even the manner of making it
- Article of manufacture claim elements: The preamble of an article of manufacturer claim usually just names the article, e.g., "a resistor comprising..."

 35 USC §112 ¶6 may be invoked to use means-plus-function clauses for broadly specifying some elements ("means for attaching A to B"), but as with all such clauses, at least one component must presently exist that can perform this function
- Product-by-process claims: This claim defines a patentable product by the process of fabricating it or its elements (e.g., "sodium hydroxide produced according to the process of claim 1") this style may be used for one component of the article (e.g., "a resistor comprising... (b) a coating of carbon deposited on the core by decomposition of a hydrocarbon gas") the claim is only allowable if the product has some novelty; the claim cannot describe a known product where all or part is

made by a conventional process, as the process is used solely to identify the product (In re Brown & Saffer (1972)) – the old rule was that such claims are allowed "only where the product cannot be described in any other manner," and only permitted one such claim in an application; no such restrictions now exist (Leutzinger v. Ladd (1963)) – product-by-process claims should not include any specification of structure, and in fact this may render the claim invalid (In re Pilkington (1969): a product claimed as "an acid phosphate of a condensation product of a formaldehyde... made by the process..." was construed as an invalid product-by-process claim, because the "condensation product" terminology implied structure; other findings have similarly construed "etched", "welded", "interbonded by interfusion", and "chemically engraved" as structural limitations that negate product-by-process claiming) – every method claim that produces a novel article should be considered for recasting as a product-by-process claim – product-by-process claims cover the product only when made by the process described (however, there is some precedent discrepancy: contrast *Scripps Clinic* & Research Found. v. Genentech, Inc. (1991) and Atl. Thermoplastics Co. v. *Faytex Corp.* (1992))

- Design patents: These are fairly straightforward, as only one claim is permitted: 35 USC §171-3:L "The claim shall be in formal terms to the ornamental design for the article as shown, or as shown and described" the claim may specify the kind of article on which the design is embedded, and should be the same title used in the specification the specification is very simple, merely describing the various angles from which the article is shown in each drawing, though it may also recite that certain angles are mirror images or plain the patented aspect of a design is the "overall aesthetic effect," and the design must be viewed "as a whole" to determine if such effect exists one creative "article of manufacture" into which an embedded design was patented is the stream of water from a fountain (*In re Hruby* (1967))
- Plant patents: These patents feature only one claim, but the specification may recite the "principal distinguishing characteristics" this description is largely irrelevant, and so is often set forth in decorative language (e.g., "a new and distinct variety of chrysanthemum plant of the thick decorative class, substantially as herein shown and described, characterized particularly as to novelty by the unique combination of a hardy and free habit of growth, a large bloom size, and a distinctive and attractive general color tonality of the flowers corresponding to Apricot Yellow") the plant so patented must be novel in conception, and not preexisting in nature; also, the plant must be asexually reproduced the patent need not disclose a method of making it, but infringement occurs only by using the patented stock; independently creating the same strain does not constitute infringement
- <u>Provisional patent applications:</u> A provisional application is usually filed to secure a filing date no examination occurs, but the application is automatically and irrevocably abandoned after one year no claim is required, but some examiners include one anyway, since the nonprovisional may include the claim to support a claim of priority back to the provisional, and also to ensure that the provisional is

considered a patent, and not a "non-patent publication," by stricter patent offices like the EPO

Chapter Six: Composition of Matter Claims - Chemical Claims

- Overview: Chemical claims differ from apparatus claims by focusing on the composition and materials rather than the shape or form chemicals and articles of manufacture are considered identical in claim interpretation most such inventions are sets of atoms or molecules comprising a whole composition claims are easy to prepare (just state the formula); the difficulty arises more from novelty and nonobviousness patents have even been allowed for novel elements (U.S. Pat. No. 3,161,462 (now called "curium") and U.S. Pat. No. 3,156,523 (now called "americium")
- Example chemistry claims:

A zinc electroplating solution, comprising:

- (a) an aqueous solution of zinc acetate, from 30 to 90 grams per liter;
- (b) citric acid, from 1.5 to 3 times the zinc acetate concentration; and
- (c) an alkaline pH-modifying substance in an amount sufficient to adjust the pH to a value of from 4 to 5.5.
- Chemical claim drafting: The elements of a chemical claim are the various chemical components it's valid but rare to claim them in means-plus-function format, but may be more generally claimed as in (c) above preambles containing statements of use are rarely included, because the utility is sufficiently suggested in the specification somewhat unusually, the claims may refer to a chemical structure drawing, e.g., to suggest proportions of ingredients in alloy cases
- Markush groups: A set of similar compounds may be claimed as a group, such that any of them may be mounted at a defined spot on a structural diagram to produce an invention covered by the patent this technique is used to create a generic term for a set of similar components for which no such term exists; if a generic term already exists, it's better to use it than to create a Markush group, which is restricted to the provided options e.g.:

A compound having the formula: R-CH=N-S-X, where:

R is an alkyl group selected from the group consisting of methyl, ethyl and isopropyl; and

X is a halogen selected from the group consisting of chlorine and bromine.

Markush groups are recommended by MPEP §2173.05(h) for chemical, biological, pharmacological, ceramic, refractory, and metallurgic composition inventions, and even for mechanical inventions ("a fastener selected from the group consisting of a staple, a nail, a screw...") and processes ("a process for ... comprising the steps of: weakening the bond by a process selected from the group consisting of heating, freezing, and irradiation...") – however, the claim only covers those elements featuring one instance of one selected group for the Markush element – one common use of a Markush group is to call forth a (preferred) subgenus from a (broad) genus in a parent claim – e.g., "the

- composition of claim 1, wherein the conductive metal is selected from the group consisting of steel,..."), or even to narrow the elements of a Markush group in the parent claim
- Markush group requirements: The group should be carefully selected; suggesting "halogen" and "chlorine" prompts a double-patenting rejection for obvious reasons, "comprising" cannot be used for the transition; must be "consisting of" preferably, a Markush group should always be written: "selected from the group consisting of A, B, and C" (note use of commas, and concluding "and") MPEP §2173.05(h) requires commonality among Markush group elements for groups of materials, the elements must "to belong to a recognized physical or chemical class or an art-recognized class" for apparatus and process claims, the members must only "possess at least one property in common which is mainly responsible for their function in the claimed relationship" (ideally, the commonality should be specified as the generic term: "a resting surface selected from the group consisting of a chair, a bench, and a stool"; this can also be claimed as "means for...") if commonality is violated, the examiner can raise a restriction requirement (MPEP §803.02)
- Trademarks and trade names: Such terms can be used in a patent application where they have a fixed and definite meaning, either in the art or in the specification four cases of proper use of a trade name: ordinary practitioners can make the trade-name product at the time the application is filed by using the specification or literature; the product is known to ordinary practitioners and is "readily obtainable" (its composition can be kept as a trade secret); or the trade term is used in a nonessential context in the specification a reasonableness test is usually applied to these rules in fact, the applicant may be permitted to add a description of the composition of the trade name at a later date; this does not count as new matter if the applicant files a "statement of identity" (an affidavit that the trademark name used in the application as filed is identical to the structure subsequently added)
- "Fingerprint claims": Where an applicant has produced a new composition, but cannot explain the physical or chemical structure, the composition can be claimed according to some novel identifying traits, like X-ray diffraction patterns, solubility, and melting point U.S. Pat. No. 2,482,055: "substances effective in inhibiting the growth of bacteria, comprising a substance capable of forming salts with acid, containing the elements C, H, N, Cl, and O, being very soluble in pyridine, its crystals having a refractive index between..."; the applicant had isolated this novel protein, but had no idea of its actual structure, and so claimed it by every known physical property a very specific description is sufficient to "distinctly claim" the invention (Benger Labs, Ltd. v. R.K. Laros Co. (1962)) this tactic can even reference a drawing for an essential visual property, like an imaging spectrum ("said thiostrepton having an infra spectrum substantially as shown in the drawing" (U.S. Pat. No. 2,982,689)
- <u>Coined name claims:</u> A "coined name" claim attempts to claim a composition solely by a unique name (claim 2 of U.S. Pat. No. 2,699,054 simply reads: "Tetracycline"), where the named compound is thoroughly defined in the specification, and also is already well-known in the art (*Ex parte Brian* (1958):

- claim to "alkali metal salt of gibberellic acid" rejected for using the non-art term "gibberellic," even though defined in the specification) where the method of creating a composition is well-known but its structure is not, a coined-name claim can be used in parallel with a fingerprint claim for redundant protection
- Claims referring to drawings: MPEP §2173.05(s) allows this tactic "only in exceptional circumstances where there is no practical way to define the invention in words and where it is more concise to incorporate by reference than duplicating a drawing or table into the claim" e.g., a three-composition alloy might specify ranges of composition that vary in proportion to one another; this range of compositions is difficult to claim in words, but can be handily represented as a two-dimensional chart; thus, can be claimed: "with said components restricted to amounts according to the chart of Fig. 1" broader example: U.S. Pat. No. 3,034,806 claims "a font of numerals as shown in Fig. 1"; impossible to describe such numerals in words however, this tactic requires necessity, not merely the applicant's preference (*Ex parte Lewin* (1966))
- Use claims: Some applicants attempt to claim a process of using a known material for a known purpose without further detail ("the process of using an iron alloy as a vehicle brake part"), which is indefinite and nonstatutory – the "limitation" is just a statement of purpose, such as would appear in a preamble, not a novel process – a process must possess its own novelty, rather than just being a new use of a known material in a known process in a conventional way – on the other hand, carrying out a known process using a material well-known but not obvious to use in the process may be patentable – the rule was that even if using a wellknown composition in a novel process or way can be patented as a method, it cannot permit the patenting of the well-known material as a composition (In re Thuau (1943): CCPA rejected composition claim for a known compound that was newly utilized as a tanning agent) – patentability is not conveyed if the material is added in a new solvent that does not lend any other property (Ex parte Douros & Vanderweff (1968)), or by formulating it as a tablet or capsule that lacks added novelty (contrast *In re Graige* (1951) with *In re Halleck* (1970)) – however, the general ruling in *Thuau* was called into question in *In re Duva* (1967), which suggested that a preamble limitation may create novelty for such a process, and that the claim as a whole must be considered – because these doctrines are not well-settled, it is good practice to claim a material and its use in as many forms as possible
- <u>Jepson claims for chemical inventions</u>: A Jepson claim is a claim for an improvement invention, claimed by stating a preamble describing the prior art, a transition clause ("wherein the improvement comprises"), and a description of the new or modified elements this style is recommended but not required; and while no "magic words" are necessary, it is recommended to use the term "combination" in the preamble and "improvement" in the transitional clause in order to satisfy Rule 75(e) these claims are good for differentiating the prior-art combination and the new elements, thereby avoiding "old combination" rejections the preamble of a Jepson claim is always considered a limitation (*Rowe v.* Dror (1997)) accordingly, Jepson claims bear the inherent danger of implicitly

- admitting the contents of the preamble to be prior art, but this is a rebuttable presumption (MPEP §2129)
- Generic and species claims: As an alternative to a Markush group, an application can specify a genus in generic terms, and dependently refine it into several species e.g.: an apparatus patent might specify "a support" and dependent claims might refine this as "legs" or "springs" for particularly broad elements, it may be permissible to include an intermediate "subgenus" layer this tactic differs from Markush grouping by including all undisclosed options that fit within the genus; on the other hand, a lack of commonality among species may result in a restriction requirement (in this context, an "election of species") also, each species must have its own dependent claim, whereas the Markush grouping specifies all options as alternatives in one claim
- Combination and subcombination: A patentable combination might also have a patented component, sometimes called a "subcombination" e.g., a compound that is a good insecticide might be claimed both on its own and in combination with other chemicals (e.g., preservatives and dyes) that form a commercially desirable product in order to be claimed, a subcombination must feature its own novelty; those that do not are rejected as "incomplete" or lacking utility however, claiming both in the same application often leads to a restriction requirement these can be drafted with "in an apparatus for X, an apparatus comprising Y," or in Jepson style: "an improved W for an X apparatus having old elements Y and Z, the improvement W comprising..."

Chapter Seven: Claims of Varying Scope

- Overview: An invention may be claimed by multiple claims, so long as each has at least "a mere difference in scope" (MPEP 706.03(k)); this requirement is usually invoked only in cases of considerable multiplicity of claims claims need not be patentably different, but should differ substantially in scope, aspect, etc. the goal is to assert the narrowest claim that will cover an infringer, but to include increasingly broad claims to cover as wide a variety of infringer as possible
- Claim scope: The narrowest claims should recite the structural components of the preferred embodiment ("picture claim") the broadest claim should solely include the essential components and operative details intermediate claims can then be added that add limitations to the broad claim, or broaden some terms in a narrow claim these claims can be written in any order, and different practitioners have different approaches of course, technical terminology should be completely consistent among claims
- <u>Different classes of invention</u>: The invention should be claimed from as many patentable classes as possible (e.g.: composition, process for creating the composition, process for using the composition, apparatus for producing the product, etc.) this may prompt a restriction requirement; but it's good practice to try grouping the classes together, which at least preserves the option of filing a divisional for a later date

Chapter Eight: Non-Art Rejections

- <u>Duplicate claiming and undue multiplicity:</u> MPEP §706.03(k): Rejection valid if two claims are "so close in content that they both cover the same thing, despite a slight difference in wording" a common examiner tactic is to allow one claim, and then reject the other as duplicate with the first this doctrine has been limited; as along as a claim adds, removes, or changes at least one detail, it's not considered duplicate (see *Ex parte Primich* (1966)) this rejection is usually limited to where the examiner perceives that the application contain "too many" claims for the subject invention and wants to reduce them similarly, MPEP 2173.05(n): "an unreasonable number of claims, in view of the nature and scope of the applicant's invention and the state of the art," may support a rejection of some claims as "undue multiplicity"; again, invoked in limited circumstances, and discouraged by the BPAI (*Ex parte Birnbaum*: examiner must show that multiplicity renders the claims difficult to understand) and CCPA (*In re Flint* (1969))
- Old combination and "overclaiming": This rejection used to arise where an inventor developed a novel subcomponent in a larger apparatus, and the inventor claimed the entire apparatus as novel – e.g., *Holstensson v. V.M. Corp.* (1964): USPTO rejected a patent for a record turntable that demonstrated novelty only in a spindle element – MPEP §2173.05(j) negates this kind of rejection, as does the CAFC (Radio Steel & Mfg. Co. v. MTD Prods., Inc. (1984)) – the rationale of this rejection is backwards: if an inventor invents element A in apparatus A + B + C, he limits the scope of his invention by claiming B and C as essential limitations; in fact, had the inventor deleted B and C in a reissue application, this would have been an unallowable "broadening reissue" - accordingly, this rejection basis did not apply where the inventor stated a particular use for the subcombination in a preamble clause, but did not recite any elements of the broader apparatus as claim limitations – if the invention has to engage other apparatus components, and has to reference these in the claim, they can be introduced in the preamble (In re Dean (1961): "In a camera shutter mechanism, including two shutter-actuating elements, a shuttering apparatus for improved exposure accuracy comprising: a device coupled to said shutter-actuating elements..." – the CCPA affirmed that the claim did not include the shutter-actuating elements)
- Aggregation: MPEP §2173.05(k): If fewer than all of the elements of the apparatus cooperate to achieve the result, then the invention is an "aggregation" famous aggregation case: Reckendorfer v. Faber (1875): embedding an eraser on the end of a pencil rejected as an aggregation again, this rejection basis has been weakened: the same MPEP section notes that aggregation rejections "should only be made after consideration of the court's comments in In re Gustafson," which merely reads "aggregation" as a ground of rejection is nebulous and has no basis under the Patent Act of 1952" by contrast, In re Venezia (1976) allowed a patent claim to a kit of unassembled parts that could be assembled into a working invention also, Ansul Co. v. Uniroyal, Inc. (1971): chemical compositions containing unrelated chemicals could not be rejected as an "aggregation"
- <u>"Printed matter"</u>: MPEP §706.03(a): "a mere arrangement of printed matter, though seemingly a 'manufacture,' is ejected as not being within the statutory

- classes" if the printed material is a functional component of an apparatus, this rejection is inapplicable (*In re Miller* (1969): claim allowed for a patent to a measuring spoon with a measuring/conversion legend attached) in essence, printer matter should be included as a claim element where it renders the claimed invention operative; even though the printed matter is nonstatutory on its own, it's allowable as an element of a broader invention
- <u>Incompleteness:</u> MPEP §2173.05(l): An invention is "incomplete" "if it omits essential elements, steps or necessary structural cooperative relationship between elements" this sounds more like a rejection because the claimed invention is inoperative this rejection may arise where the practitioner has eliminated nonessential elements to broaden the claim, but this tactic is fine as long as the claimed invention still works (*Ex parte* Schaefer (1970)) obvious response: add a new claim incorporating the purportedly missing elements
- "Vague and indefinite": A claim that does not "particularly point out" or "distinctly claim" the invention may be rejected as vague under 35 USC §112 ¶2 vagueness may be created by lack of antecedent basis, failure to read on a disclosed embodiment, too little detail about elements or interactions, or careless use of words of degree (how much is a "sufficient" amount of a component of a composition claim?)
- Prolix: MPEP §2173.05(m): Prolix rejections are proper for "very long detailed claims setting forth so many elements that invention cannot possibly reside in the combination" rather than reciting a host of new elements in an invention, I t would be better to include dependent claims that progressively add elements that narrow the invention
- New matter: MPEP §706.03(o): An inventor cannot add "new matter" to the specification, drawings, or claims after the application has been filed unless the new matter is supported by the original disclosure e.g., a claim cannot be amended to eliminate an element that the specification declares as essential

Chapter Nine: Claiming Biotechnology Inventions

- Overview: Biotechnology involves the commercial use of living organisms, and includes genetics, molecular biology, biochemistry, microbiology, virology, etc. particularly important technologies include recombinant DNA and highly specific monoclonal antibodies
- Patentability of living organisms: Diamond v. Chakrabarty (1980) affirmed the patentability of novel living organisms, and the USPTO has extended the broad ruling of this case to allow patents for novel seeds and plants (not just under the Plant Patent Act and the Plant Variety Protection Act), and for multicelular organisms (see *In re Allen* (1985) for a patented oyster, and U.S. Pat. No. 4,736,866 for a patented mouse, claimed as "a transgenic non-human mammal") the only non-patented animal is a human being, which is considered implicit in Amendment XIII to the U.S. Constitution and was made explicit in 2004 as the "Weldon Amendment" claims for organisms are difficult, whether pointing out the organism by its genotype or phenotype common claim style: U.S. Pat. No. 5,484,956: "A fertile transgenic *Zea mays* plant of the R0 generation containing heterologous DNA encoding *Bacillus thuringiensis* endotoxin, wherein said DNA

- is expressed so that the plant exhibits resistance to an insect" also patentable (and less controvertible) are claims for methods of making recombinant or transgenic plants (U.S. Pat. No. 5,384,253: "A method for producing a transgenic *Zea mays* plant comprising…")
- Claims based on biological deposit: Where an organism cannot be claimed with the level of detail required by 35 USC §112, or where the use of an organism cannot be tested by the public or examiner, the inventor can make a biological deposit and claim with reference to it (37 CFR §§1.801-1.809) U.S. Pat. No. 4,292,406 specification: "The newly discovered thermophilic anaerobes were isolated in biologically pure cultures... a representative strain of this new microorganism in a biologically pure subculture has been deposited in the patent strain collection of the American Type Culture Collection...")
- Claims to nucleic acids and proteins: The nature of genetics and protein production should be considered when drafting patent claims to a novel protein or nucleic acid sequence a claim reciting a sequence may depend from a broader claim to the protein described in other terms (U.S. Pat. No. 5,443,825: "1. Purified and isolated human leukemia inhibitory factor (LIF) which is substantially free of other human proteins. 2. Purified and isolated human LIF, according to claim 1, having the amino acid sequence set forth in FIG. 26..."); this is good practice for broader claim scope, in light of the degenerate nature of DNA translation and the ability to substitute some parts of a protein without affecting its structure even better may be a dependent claim to the protein as having a short sequence of amino acids comprising essential components (e.g., the amino acids that form a binding site) of course, such patents usually claim both the DNA sequence and the protein product the rules for amino acid and DNA sequence listings set forth in 37 CFR §§1.821-1.825 must be carefully followed (CD-ROM submission, numbering of sequence IDs, etc.)
- Novelty of biotechnology inventions: Due to the maturing of biotechnology, patent examiners are more often rejecting applications based on anticipation e.g., a claim to the product of a recombinant DNA use has been rejected under anticipation if the protein is fully characterized in the relevant literature (*In re Spada* (1990)) of course, claim to DNA are subject to all of the usual rules of patentability; e.g., a DNA sequence is anticipated by prior publication of that same DNA sequence (*Ex parte D* (1992)), and the DNA sequence must be described in more specific terms than its functional utility (*Amgen, Inc. v. Chugai Pharm. Co., Ltd.* (1991))
- Obviousness of DNA inventions: The USPTO used to cite general methods of synthesizing DNA in rejecting claims to a DNA sequence encoding a particular protein, but this is now regarded as insufficient basis (*In re Bell* (1993), reaffirmed in *In re Deuel* (1995): "the existence of a general method of isolating cDNA or DNA molecules is irrelevant to the question of whether the specific molecules *themselves* would have been obvious, in the absence of other prior art that suggests the claimed DNA") thus, the fact of "obvious to try" coupled to a known method of doing it are together insufficient for obviousness this is most relevant to the patenting of monoclonal antibodies

- Obviousness of bioechnology process inventions: The process of using a biological composition for a novel purpose is broadly patentable (In re Pleuddemann (1990), relying on In re Mancy (1974) for distinguishing methods of making and methods of using biological materials) – however, the use of a well-known method for producing a specific protein or the product of a specific DNA sequence was long considered per se obvious (In re Durden (1985)) – techniques rejected under this rationale include (a) purification processes, (b) methods of preparing monoclonal antibodies for specific antigens, and (c) methods for making a gene product by genetic engineering – many biotechnology companies seek these claims because of the Process Patent Amendments Act of 1988, which allows U.S. patentees to enforce the patent against an overseas manufacturer who export unpatented materials to the U.S. made abroad via a patented process – *Durden* and the CAFC rationale were expressly reversed by the Biotechnology Patent Process Protection Act of 1995, newly adding 35 USC §103(b), which defines as nonobvious any biotechnology process that produces a novel invention – simultaneously, the CAFC reversed its holding on this issue (In re Ochiai (1995))
- Sufficient written description and utility of nucleic acid: In order to support the particularity requirement of 35 USC §112, and (more importantly) to support a claim of priority, "the specification must 'reasonably convey to the artisan that the inventor had possession at that time of the [making of the invention that he had possession of the] claimed subject matter" (*Fiers v. Sugano* (1993)) this requirement is not met by a bare recital of a DNA sequence, which is merely "a wish, or arguably a plan, for obtaining the DNA" also, the USPTO has previously rejected as lacking novelty the identification of gene sequences that will be used to research health conditions, i.e., as research tools this decision prompted controversy, leading to the USPTO's Utility Examination Guidelines (2001), defining the requirement of utility as a three-part test: specificity (the protein must be used to research a specific disease), substantiality (the protein must have "real world" use; e.g., a protein useful solely for studying its own structure is not patentable), and credibility (the person of ordinary skill in the art would accept that the protein is compatible with its claimed use)
- Enablement for DNA and protein claims: The USPTO regards proteins as subject to considerable functional changes with small structural changes thus, a patent claiming a modification of a protein must support that claim with a specification sufficient to enable one of ordinary skill to make and use the invention without undue experimentation Ex parte Mark (1989) involved a claim to all proteins that have at least one naturally-occurring cysteine to be substituted with another amino acid without functional changes; BPAI allowed the claim because of a thorough and sufficient specification also, the USPTO recognizes the high unpredictability of the field, and only allows broad claims where supported by many examples proving enablement throughout the claimed domain
- Patentability of monoclonal antibodies: Many inventions can exist in the context of a monoclonal antibody: the hybridoma cell line, the antibody secreted by it, the method of making the antibody, the method of using the antibody (immunoassay), and an immunoassay kit incorporating the antibody the antibody must be

- described with sufficient clarity, either by its target ("antibody reactive with leukocyte interferon") or its functional use ("antibody that binds to human breast adenocarcinoma cells, but not to non-cancerous human breast epithelial cells") however, patentability of monoclonal antibodies has been limited to those exhibiting novel specificity for a particular antigen, or those made via a particularly inventive process (*Ex parte Erlich* (1986/1992) and *Ex parte Sorg* (1992))
- Patentability of therapeutic methods and compositions: Therapeutic claims must be for the treatment of a specific disease or condition, and must be supported by experimental evidence of success the CAFC has held that *in vitro* evidence can be sufficient by itself (*Cross v. Iizuka* (1985)); however, the burden of proof of therapeutic use within the USPTO (*Ex parte Balzarini* (1991): BPAI suggested that antiviral compounds may need even clinical trials to support a patent claim) successful testing in animals is sufficient if the animal is recognized as a good model for the condition in humans (*In re Krimmel* (1961)) the USPTO limited this rising trend by passing a new set of guidelines instructing examiners to consider utility fulfilled by evidence of a reasonable use for public benefit and an reasonable correlation between the pharmacological activity of a compound and the therapeutic use; the USPTO expressly rejected the necessity of human clinical trials, and the CAFC affirmed (*In re Brana* (1995))
- <u>Patentability of gene therapy methods:</u> Gene therapy methods (both in vivo and in vitro) are patentable under the same conditions as other biotechnology patents, but this is an emerging field at least one inventor has attempted a broad patent on the entire field (U.S. Pat. No. 5,399,346), but this is likely to be rejected

Chapter Ten: Thoughts on Writing a Claim

- Goals of claim writing: The claims should cover the invention, as broadly as possible, in light of its operative concept and objective the claims should cover the disclosed embodiments, and all expected and unexpected equivalents, so that a competitor can't design around the patent by making a trivial change; in essence, any invention that embodies the inventive concept, and any invention that achieves the same result by a similar mechanism, should be covered the only limits on the scope of the invention should be the prior art and the formal requirements of the USPTO
- <u>Broad claim structure:</u> First, the invention should be claimed from as many perspective as possible (a method invention should include apparatus claims, and vice versa; the invention can be claimed as a set of structural or functional means, or a hybrid; any novel component of the invention should be considered for its own novelty; if the invention works on a material in a novel way, perhaps this can be claimed as a submethod, or a subcombination apparatus; product-by-process claims should be included for all methods that produce novel products; etc. all claims should be oriented to achieving each goal of the invention each feature or objective should be fully covered by a set of claims, possibly beginning with an independent claim (the examiner may issue a restriction requirement, but it's worth it to try)

- Writing a broad claim: Apparatus claims should be written in mind of the most relevant figures; this permits accurate descriptions of the components and their interaction, and ensures that the claims cover it conversely, every essential feature in the drawing should be present in at least one of the claims unnecessary elements should be removed, but of course, no element that is necessary for the operation of the stripped-down invention should be eliminated apparatus claims should also consider the sequential operation of the overall process, and might claim the apparatus with one means element for each step a very well-written apparatus claim may be able to teach the operative concept to the reader without reference to the figures
- Claiming individual claim features: First, assign the element a unique name, both to describe it in the claim and to establish antecedent basis to the specification use of the same term (but note that the element is not limited as the specification suggests, but only as the claim indicates) – the name should be related to the component function, but not in any particular guise (e.g., an "anvil" is only useful for its surface; this element can be claimed as a "surface," with the specification suggesting the use of an anvil (in the specification, "an anvil having a surface on which the workpiece is worked") – claiming the element as a means is permitted, but overutilizing §112 ¶6 can damage the readability of the claims – next, describe the location and role of the component in the apparatus or article, including previously named articles with which it necessarily cooperates – in more complicated apparatuses, it may be helpful to describe the interaction between two elements past the description of each of them (e.g., when they cooperate with a third element discussed later in the claim) – statement of function: where a component cooperates with another to achieve a function, this function should be stated ("a motor connected with the shaft for driving the shaft to rotate"); if it's not required, don't add it
- Revising the claim: After all of the claims have been written, review the claim set: remove elements unnecessary for achieving the inventor's goal, especially in independent claims (try considering how the claim would work if each element were removed); delete dependent claims too focused on minute details; refactor dependent claims reciting a number of limitations into a set of smaller dependent claims; consider using a generic name for elements more specifically named, especially for many elements named in the alternative; remove connection means to components that have been eliminated
- <u>Alternative claim-drafting techniques:</u> An apparatus can be claimed as a generic set of operative elements, each subsequently defined in more detail through dependent claims alternatively, the invention can be described as a "catalog of parts," and the practitioner can later select them for inclusion in a claim
- Claiming multiple embodiments: First, draft a generic claim that covers all of the embodiments based on their common thread, and write a broad claim with minimal structural limitations that completely performs the invention the specific embodiments can be differentially covered in dependent claims if one embodiment bears features that the others do not, a separate independent claim can be written for it; or, one generic independent claim can be mentioned, along with subgeneric claims, one of which mentions the additional benefit and

- limitation if the subgeneric inventions are sufficiently distinguished, the examiner may issue a restriction requirement, but it's worth avoiding enough claims should be included to cover every embodiment, but claims should probably not add needless detail not related to the actual invention however, very detailed claims may more reliably pass scrutiny during litigation, may be easier to obtain an allowance, and may require a designing-around competitor to make more changes from the preferred embodiment
- Claiming an important function in a product claim: If the invention achieves an important result, the result should not be claimed as an objective ("a woolen cloth having a tendency to wear rough rather than smooth"); rather, the claims should reflect a structure or function that must be used to accomplish the objective ("a woolen cloth comprising a first layer of...") a "whereby" clause can state the necessary outcome and desired result of the preceding statement of cooperating elements, but not to add a structural limitation (attempting to do so suggests a missing element) thus, the "whereby" clause shouldn't alter the patentability of the invention, but should clarify the overall result for the reader
- The means clause: This clause should describe the functional role of an element in the invention – this is interpreted more broadly, but may ensuare prior art to invalidate the patent – as discussed, always use "means for" or "step for" to introduce the clause (not required, but good practice; some cases have denied §112 ¶6 interpretation for clauses using alternative language: see *Cole v*. Kimberly-Clark Corp. (1996)) – equivalency under §112 ¶6 is determined differently than under §102 and §103 (In re Donaldson Co. (1994)) – the doctrine of equivalents helps expand rights based on the "substantiality" of differences, and considering the prosecution history and prior art - §112 ¶6, by contrast, limits interpretation of a claim element to equivalents in structure, material, or action, and looks only to the accused component "functions identically and is merely insubstantial change that adds noting of significance" to the means clause in the patent (Durable, Inc. v. Packing Corp. of Am. (1994)) - means clauses are particularly useful where a structural element fulfills two purposes; reciting both may be confusing, so the structural element can be separately claimed as two or more means elements, with dependent claims clarifying the use of the structural element for both functions (this also ensnares competitors who attempt to design around by using a different element for each purpose) – while "means" should not be mechanically added after generic nouns, it is appropriate to do so when the function may be embodied by multiple pieces (several blades working together can be claimed as "blade means") – particularly in software patents, an apparatus component might be claimed as "means"; this suggests the use of a physical component, rather than an algorithm – however, in In re Alappat (1994), the CAFC affirmed that a general-purpose computer may be used to satisfy one of the "means," thereby suggesting the creation of a new apparatus by programming a general-purpose computer for a particular purpose
- Methods claims: A method claim is useful for carrying out a process not overly tied to a specific structure each step should represent an action, and should be named with a gerund ("comprising the steps of: providing a first surface; positioning a workpiece on the first surface;...") it's helpful to characterize the

process as working on some kind of article for achieving a desired process – also, the purpose to be achieved by an action should be included ("hammering the workpiece for flattening it"), unless the goal is obvious from the described action – note: in this kind of claim, the product or apparatus is not claimed, and the steps should not heavily rely on the structure of either – as noted, software methods are a patentable class of subject matter, such that a series of operational steps is a patentable process, and a general-purpose computer instructed to run the process is a patentable apparatus – dependent method claims add further limitations or to add detail to steps more generally claimed in parent claims – where one step can be described generally or by a more specific process ("separating components by distilling them"), either put the more general descriptor first, or claim them in parent and dependent claims – a step can be claimed in step-plus-function form under §112 ¶6, but again, the words "step for" should be clearly used, and the claim should not suggest a specific process for carrying it out

- Article of manufacture claims: An article is like an apparatus without moving parts or claimable motion; it simply exists to serve its purpose (e.g., a shoe) its elements may still be claimed in means-plus-function form ("means for bringing together the top portion edges of the shoe," like laces, zippers, or Velcro) computer-readable media may constitute a patentable article of manufacture
- Product-by-process claims: These claims are useful where the product is novel but incapable of structural definition, or has process-related limitations it's pretty easy to write a dependent product-by-process claim referencing the process described in the parent process claim of course, the product must be novel to be patentable to be claimed as a product-by-process there is no clear precedent as to whether the process is a limitation in the claim, i.e., whether the claim covers the product as made by other processes (contrast *Scripps Clinic & Research Found. v. Genentec, Inc.* (1991) ("product by process claims are not limited to product prepared by the process set forth in the claims") with *Atlantic Thermoplastics Co. v. Faytex Corp.* (1992) ("process terms in product-by-process claims serve as limitations in determining infringement")) a majority of the CAFC seems inclined toward the latter view, but it may be resolved as a split between the two scenarios described above (difficult-to-describe substances aren't limited by the process, but products with process-specific characteristics are limited by the process)
- <u>Jepson claims</u>: The Jepson claim style is useful for inventions that are clearly improvements on prior (patented) technologies a dependent Jepson claim may reference the invention of the parent claim as an improvement in a larger prior-art invention however, this style is rarely used today in the U.S., because it's easier for the USPTO to cobble together a §103 obviousness rejection by reducing the threshold for combining references, as the prior art is admitted to be close and well-known