Biotechnology/Chemical/Pharmaceutical Customer Partnership

Tuesday, June 2, 2009
United States Patent and Trademark Office
Madison Auditorium

Morning Session

10:00-10:15	Greetings and Overview	John LeGuyader, Remy Yucel, Michael Wityshyn, Directors, Technology Center 1600
10:15-11:00	First Action Interview Pilot Program	Wendy Garber Director, Technology Center 2100
11:00-11:45	Prosecution Tips and New Initiatives	Mark Polutta Legal Advisor, Office of Patent Legal Administration
11:45-12:00	Break	
12:00 – 12:45	Written Description Chemical Practice	Bennett Celsa QAS, TC1600

Lunch
12:45-2:00

Afternoon Session

2:00-2:45	35 USC 112, 2nd Paragraph Issues	Julie Burke QAS, TC1600
2:45-3:30	Written Description Antibodies	Bennett Celsa QAS, TC1600
3:30-3:45	Break	
3:45-4:30	Inherency	Jean Witz QAS, TC1600
4:30-4:45	Closing Remarks/Discussion	John LeGuyader, Remy Yucel, Michael Wityshyn, Directors, TC 1600

First Action Interview Pilot Program

Biotech Customer Partnership Meeting
June 2, 2009

First Action Interview Pilot Program

Pilot Program Objectives:

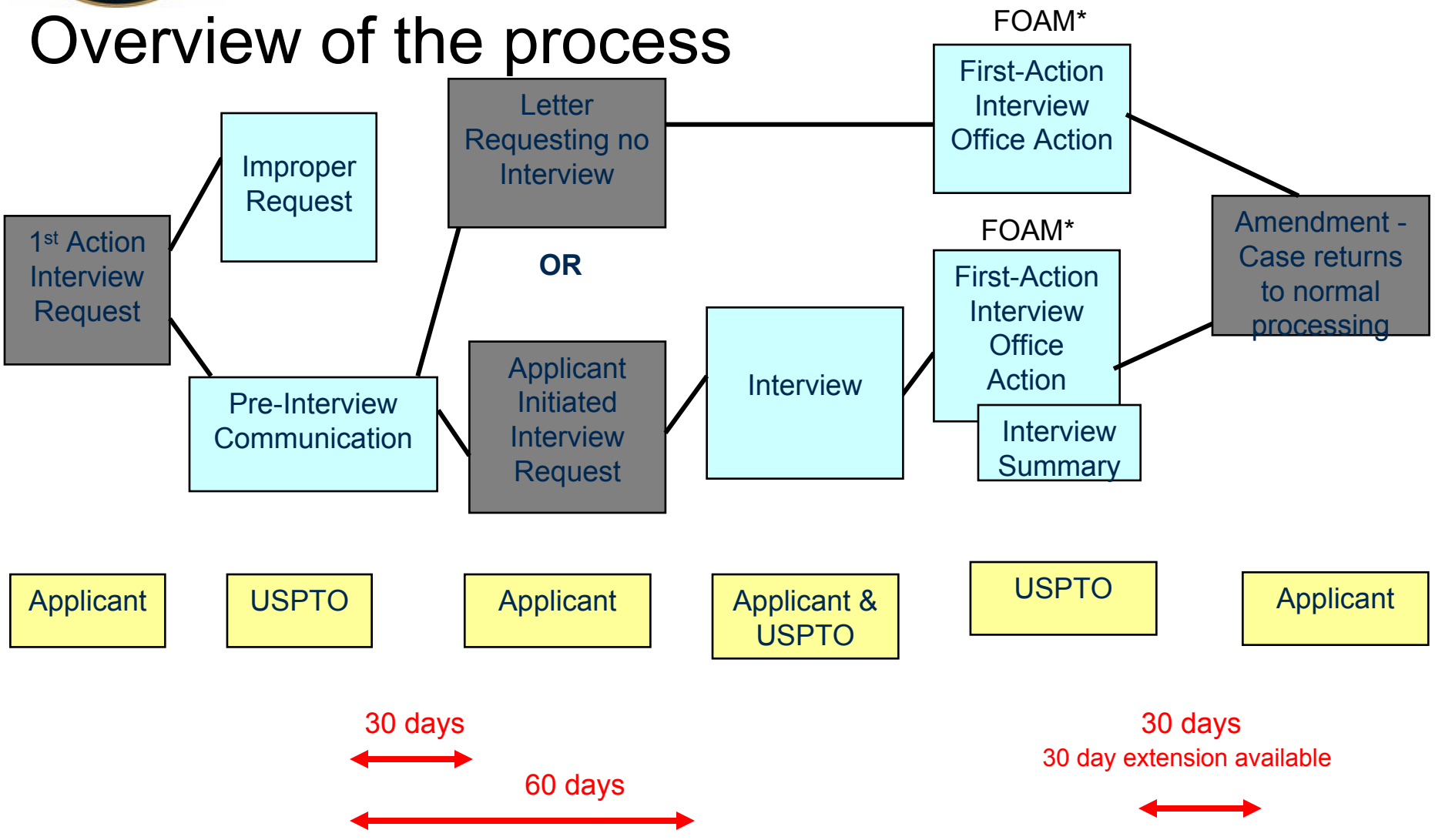
- Promote personal interviews prior to issuance of a first Office action on the merits
- Advance examination of applications once taken up in turn
- Facilitate resolution of issues for timely disposition of an application

First Action Interview Pilot Program

- Some of the current criteria:
  - Utility applications assigned to certain classes and art units
    - Including national stage applications under 35 USC 371
    - Excluding design, plant, and reissue applications
  - The application contains:
    - No more than three independent and twenty total claims; and
    - No multiple dependent claims
  - The request to participate in the pilot program must be filed before the mailing of a first Office action on the merits
- The Office is considering an expansion of the pilot (requests stopped being received 10/21/08)

First Action Interview Pilot Program

Overview of the process



* FAOM – first action on the merits

Sample Pre-Interview Communication
found at http://www.uspto.gov/web/offices/pac/dapp/opla/preognotice/fai_example_1.pdf

Pre-Interview Communication

Example 1

Application No.	Applicant(s)	
XXXXXXXXX	XXXXXX	
Examiner	**Art Unit**	Page 2 of 2
XXXXXXX	XXXXXX	

Notification of Potential Rejection(s) and/or Objection(s)

#	Claim(s)	Reference(s) (if applicable)	Rejection Statutory Basis	Brief Explanation of Potential Rejection
1	1-8		101	Claim 1 recites a binary translator with various components. The binary translator as claimed is software per se and software is not considered patentable subject matter. Claims 2-8 depend on 1 and do not include hardware so as to overcome the rejection.
2	1-8		112, 1st	Claim 1 recites the limitation of "replace disabled legacy binary instructions with native instructions". However, according to the specification, on page 6, lines 1-3, "…used to disable… insert new native instructions without (see continuation below)
3	1-5, 7-8	U	102(b)	Claim 1 (Figure 1, 1st para, 3rd para, Section "3.1 Components", 4th &5th paragraph - note the claimed "processor means" is interpreted as the CPU in fig. 1); 2 (Fig. 1); 3 (Section 3.1, 4th para); 4 (section 4.2, para 9 - note this) (see continuation below)
4	6	U,V	103(a)	U does not disclose said native instruction processor as claimed. V discloses this at section 2.1, 2nd paragraph. As one would want to to have better code for hot spots in order to improve performance (see V, section 2.1), it would have (see continuation)

Expanded Discussion/Commentary

2		altering the original legacy instructions." Thus, the specification does not disclose replacing disabled legacy binary instructions. On the contrary, the specification specifically discloses not altering the original legacy binary instructions. The claim limitation of claim 1 contradicts with what the disclosure describes. Thus, this subject matter was not described in the specification in such a way to enable one skilled in the art to make and use the invention without undue experimentation.
3		section states that "any kind of memory can be used"); 5 (Section 3.1 5th para); Claim 7 (Section 3, Resourceable and Retargetable Binary Translation); 8 (Section 3.1, 4th para).
4		been obvious to include the native instruction processor in the system described in V.

DATE:	Examiner Signature:	Primary Examiner Signature:

First Action Interview Pilot Details

Applications Eligible for the Pilot

1. Subject Matter Eligibility
   - Two technology areas in TC2100
     - Computer networks (now in TC2400)
     - Database and File Management
2. Filing Date Eligibility
   - Each technology area had filing date requirements

➢ **Overall, approximately 5500 applications were eligible.**

First Action Interview Stats
as of 5/29/09

- 493 Requests to join the pilot were received
  - This represents approx 9% of eligible applications
- 376 Pre-Interview Communications mailed
- 285 Interviews held
- 240 First-action interview Office actions mailed

First Action Interview Stats
as of 5/29/09

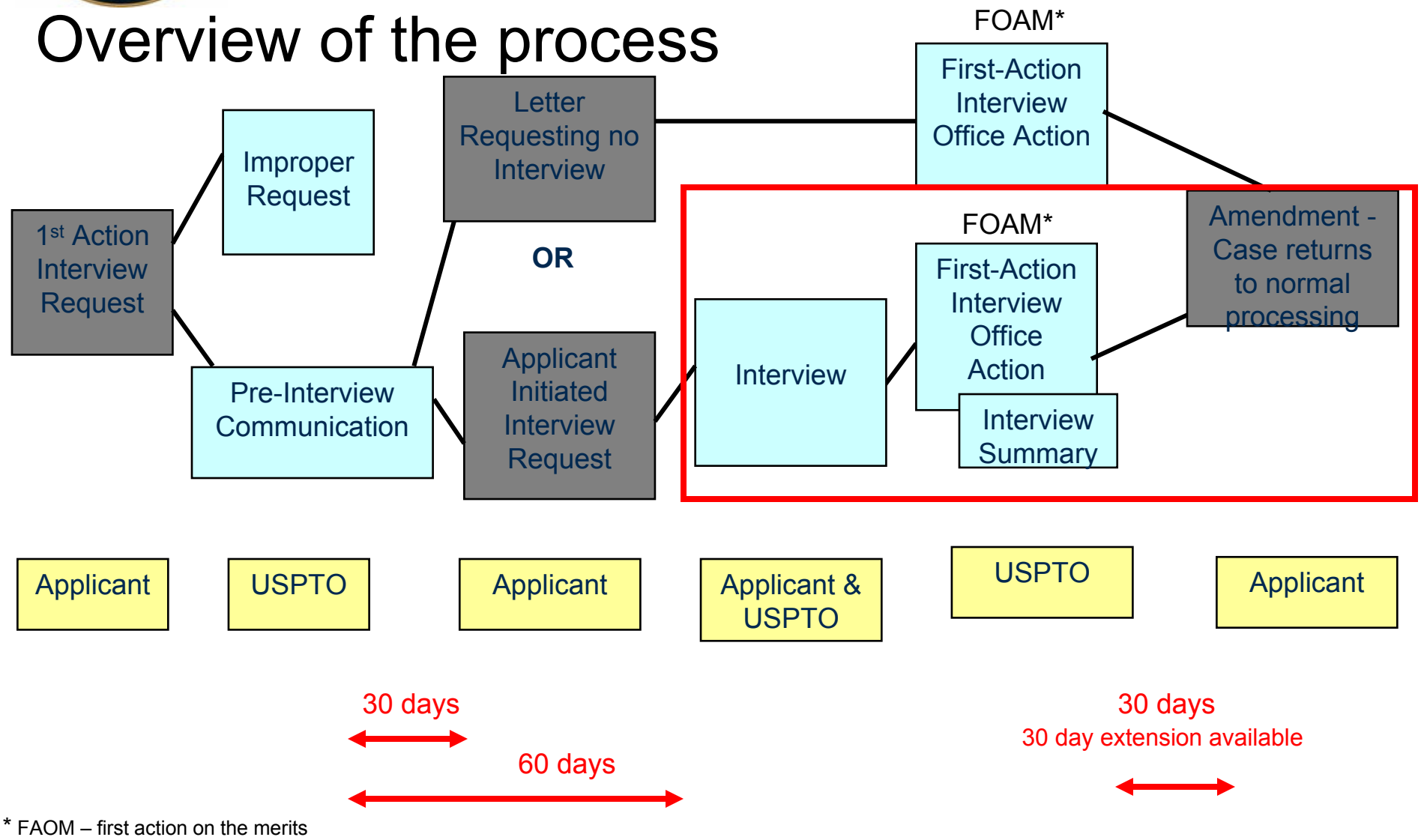
- 88 applications have been allowed
  - 26 allowed without/before pre-interview communication
  - 46 allowed after pre-interview communication but before FAI Office action
  - 16 allowed after FAI Office action
- Thus, so far, 23% of applications are allowed prior to First-Action on the merits
  - Typical first-action allowance rate in 2100 is approx 3.9% (excluding CONs and RCEs)

First Action Interview Pilot Next Steps

- Expand pilot into other technology areas
  - POPA agreed to a limited expansion
- Automate more of the application processing and tracking
- Consider allowing extensions of time to respond to Pre-Interview Communication
- Give applicants the opportunity to waive the First-Action Interview Office Action
- Surveying the applicants

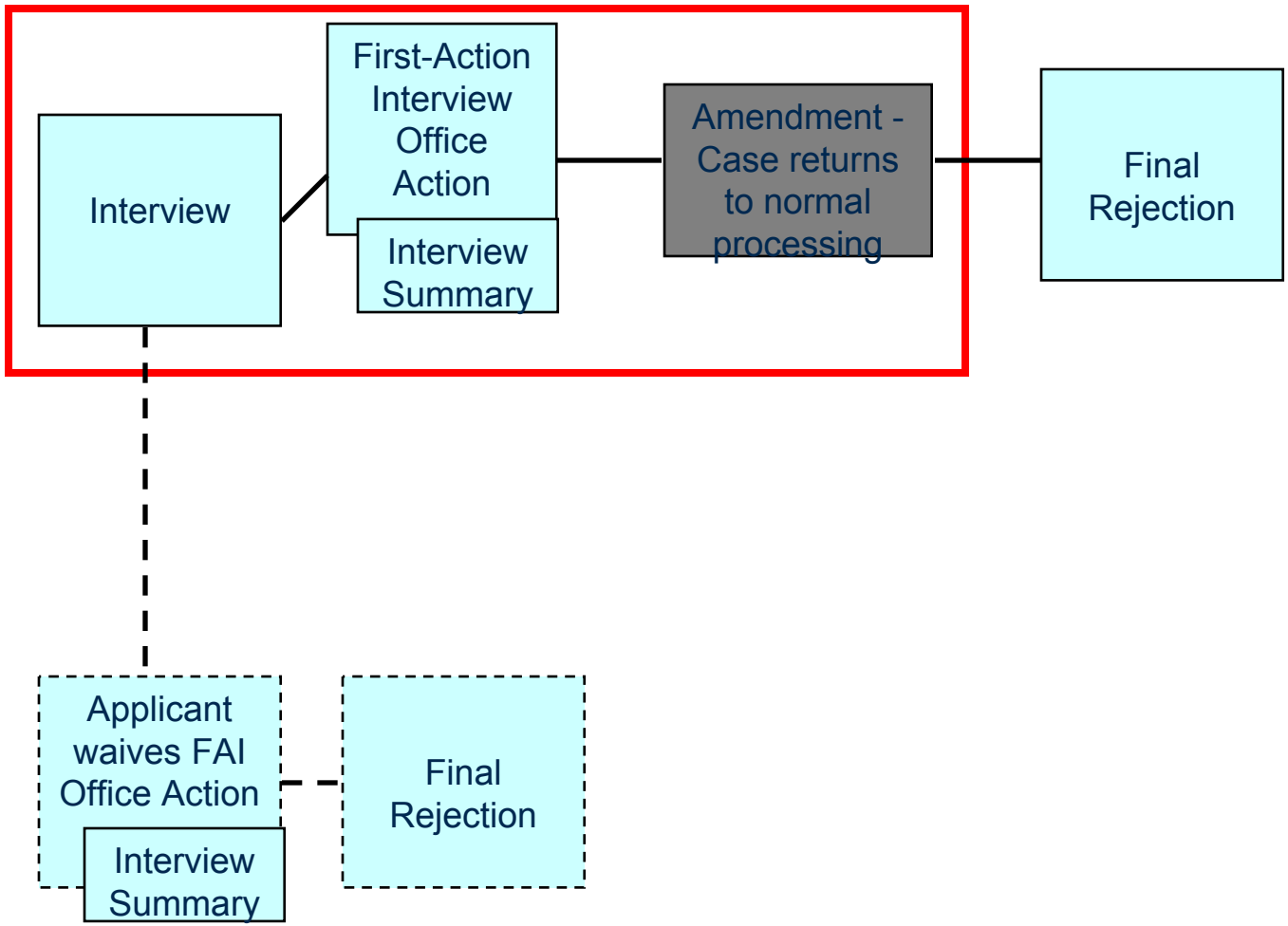
First Action Interview Pilot Program

Overview of the process



* FAOM – first action on the merits

First Action Interview Pilot Program – process change



First Action Interview Pilot Program

- Contacts
  - Joseph Weiss
    - First.Action.Interview@uspto.gov
  - Andrew Hirshfeld
    - Andrew.Hirshfeld@uspto.gov
  - Wendy Garber
    - Wendy.Garber@uspto.gov
  - John Follansbee
    - John.Follansbee@uspto.gov

Biotechnology, Chemical & Pharmaceutical Customer Partnership

Patent Practice Tips

Mark Polutta
Senior Legal Advisor
Office of Patent Legal Administration

Avoid Mistakes Throughout Prosecution

§Tips and Suggestions

- Filing the Application
- Avoiding Publication Pitfalls
- Examination Processing Tips
- Post Allowance Tips
- Best Practice Tips
- Signatures
- Withdrawing from representation

Forms

- Although use of PTO prepared forms is not required, it is advisable to use and not to alter the language.
- If a form is altered for use by a practitioner, the statement regarding approval and the OMB number must be removed.
- Do not use a combined declaration/power of attorney form, use separate declaration and separate power of attorney forms.
- USPTO forms can be found at: http://www.uspto.gov/web/forms/index.html

Application Data Sheets

Do use an Application Data Sheet (ADS), although an ADS is not required. Customers using an ADS can expect two advantages when applying for a patent:

1. Improved accuracy of filing receipts. The need for corrected filing receipts related to USPTO errors will be significantly reduced.
2. Accurately recorded application data. This will also reduce application prosecution delays and will improve the accuracy of bibliographic data in patent application publications.

Changes to a benefit claim, inventor name, etc. are simpler to perform if an ADS is used.

Application Data Sheets (Cont'd)

- Use of a supplemental ADS is possible even though no original ADS was submitted on filing.
- The following information can be supplied on an ADS:
  - Application Information
  - Applicant Information
  - Correspondence Information
  - Representative Information
  - Domestic Priority Information
  - Foreign Priority Information
  - Assignment Information

Preliminary Amendments In New Applications

- Avoid submitting Preliminary Amendments on filing
- A substitute specification will be required if a preliminary amendment present on filing makes changes to the specification, except for:
  - Changes to title, abstract, claims or addition of benefit claim information to the specification
  - See the notice "*Revised Procedure for Preliminary Amendments Presented on Filing of a Patent Application*," 1300 *Off. Gaz. Pat. Office* 69 (November 8, 2005), available at:

http://www.uspto.gov/web/offices/com/sol/og/2005/week45/patrevs.htm

Preliminary Amendments in Continuations and Divisionals

- Avoid submitting Preliminary Amendments on filing a Continuation or Divisional
- Avoid Preliminary Amendments that cancel all the claims and add new ones

Filing the Application

Select a method of filing the application

1. Accelerated Examination
2. EFS-Web
3. Traditional Mail Route

Accelerated Examination Common Failings

- Failure to provide the text search logic. A mere listing of terms will not suffice.
- Failure to search the claimed invention. The petition for accelerated examination may be dismissed if the search is not commensurate in scope with the claims.
- Failure to show support in the specification and/or drawings for each limitation of each claim.

Accelerated Examination Common Failings (Cont)

- Failure to show support in the specification and/or drawings for each limitation of each claim for every document whose benefit is claimed.
- Failure to specifically identify the limitations in each claim that are disclosed in each reference.

Filing the Application

EFS-Web Filing

- Avoid coding (identifying) a Request for Continued Examination (RCE) as an "Amendment" when filing an RCE
- Avoid identifying papers after the initial filing as "new"
- Avoid common PCT filing mistakes
- Avoid filing color images or images that have a resolution higher than 300x300 dots per inch (dpi)

Avoid Publication Pitfalls

Nonpublication Requests

- When filing a utility or plant application, conspicuously **request non publication** if
  - the invention **has <u>not</u> been** and **will <u>not</u> be** the subject of an application ***filed*** in another country (or under multilateral international agreement) that requires eighteen-month publication
    - consider using PTO form PTO/SB/35
    - a non publication request after filing is not permitted.
    - Avoid inconspicuous requests for nonpublication.
- Publication will generally include all preliminary amendments submitted in time to be included in the publication.
- If amendments to the specification are desired to be included in the publication, submit a substitute specification.

Publication Corrections

- Corrected Publication 1.221(b) - timeliness and materiality – applicants often file requests that are late and fail to recite material errors.
- Practitioners must include the assignment information in the transmittal letter or ADS or else the publication will not contain such information.
- Review the filing receipt promptly so that corrections can be requested before publication or export of data for publication.

General Prosecution Advice

- Amendments to the claims and/or specification should be accompanied by a written statement indicating specific support for the change. If the support is implicit, an explanation is beneficial.
- In response to restriction requirements, where inventions are indeed patentably indistinct, applicants should present arguments to that end.
- Read the entire prior art reference cited by the examiner, not just the part relied upon by the examiner in the rejection.

Prosecution Tips

- Proofread claims for clarity and precision
- Present all cogent arguments and evidence before final rejection
- If the examiner is believed to be ignoring a claim limitation, a personal or telephonic interview may facilitate the prosecution to completion.
- Don’t initiate a response on the absolute last day of the statutory period, if possible.
- Don’t personally attack the Examiner in a response to Office Action.
- Follow the chain of command for assistance:
  - First, call the Examiner.
  - If he or she is non-responsive or unavailable, contact the Supervisor.
  - If the issue is still not resolved, contact the Technology Center Director.

Examination Processing Tips

Pre-Appeal Brief Conference

- Avoid sending the request separate from the Notice of Appeal. Request must accompany the Notice of Appeal.
- Avoid making a request when there is an outstanding after-final amendment.
- Avoid attaching more than five pages to the cover form.
- Avoid sending in a supplemental request.
- If prosecution is reopened and another final rejection is made, there is no need for a second Notice of Appeal fee if the application is again appealed.
- Avoid submitting an after-final or proposed amendments with the request or on the same day as the request.

Filing of Continuation-in-Part (CIP) Applications

- Consider prosecuting an improved CIP invention independently of the prior invention:
  - File, if need be, a continuation only to the original invention, or take an appeal on the original invention, and
  - File a new application, rather than a CIP, for only the new invention:
    - without a benefit claim (35 U.S.C. §120, 37 CFR § 1.78) to the initial application, and
    - therefore without shortening the patent term of the initial invention if it were to be included in the CIP application, as
    - any benefit claim in a CIP cannot protect the new invention.

Issue Fee Payments

- Avoid filing an Information Disclosure Statement (IDS) after payment of the issue fee.
  - File an IDS filed after payment of the issue fee with a Petition for Withdrawal from Issue (37 CFR 1.313(c)) and an RCE (37 CFR § 1.114). Otherwise, the IDS will be placed in the file and the cited documents will not be considered by the examiner.
- Avoid delays in paying the issue fee.
  - The issue fee payment may be submitted via facsimile to the Office of Patent Publications ((571) 273-2885) or EFS-Web to ensure the payment is received within the non-extendable time period set forth in the Notice of Allowance and Fee(s) Due (PTOL-85).

Withdrawal from Issue

- Petitions to Withdraw from Issue may be hand carried or sent via facsimile to the Office of Petitions.
  - Hand carries should be brought to the security guard station of the Madison West building, 600 Dulany Street, Alexandria VA 22314.
  - The facsimile number for the Office of Petitions is (571) 273-0025.

Note: All other types of petitions must be directed to the Central FAX ((571) 273-8300).

Best Practices

- Priority Document Exchange Tips
  - Have the authorization to permit access signed by an authorized party in accordance with 37 CFR 1.14(c).
  - Only the designated attorney or agent in the provisional may grant permission to access the provisional application.

Fee Payment Tips

- Avoid placing a stop payment on a check for USPTO services or to circumvent the rules of practice. This action is not appropriate.
  - Request a refund (37 CFR § 1.26) where fees were paid by mistake or in excess of the amount required.
- Avoid drafting a check to the USPTO for services on an account with insufficient funds.
  - Ensure that the account from which the check is drawn contains sufficient funds prior to submitting the check to the USPTO.
- Do use a Deposit Account Number on a transmittal form authorizing payment
  - Do not use a Customer Number to authorize payment of fees.
- Be clear with payment authorization statements.
  - Avoid contradictory statements on payment.

Maintenance Fees/Deposit Accounts

- Maintenance fees and replenishing of deposit accounts at the USPTO can be done online: https://ramps.uspto.gov/eram
- Inquiries related to deposit accounts, maintenance fees and refunds may be directed to the Office of Finance (571) 272-6500.

2 Types of Permitted Signatures 37 CFR § 1.4(d)

- Handwritten (personally signed) signatures are provided for in § 1.4(d)(1).
- S-signatures are provided for in § 1.4(d)(2):

> An S-Signature is a permitted type of signature between forward slash marks that is not handwritten (§ 1.4(d)(1)).

Note: Samples of acceptable signatures are posted on the Office's web site:

www.uspto.gov/web/offices/pac/dapp/opla/preognotice/sigexamples_alt_text.pdf

S-Signatures – 5 Requirements 37 CFR § 1.4(d)(2)

- The S-signature must consist only of letters (including Kanji, etc.), or Arabic numbers, or both, and appropriate spaces, commas, periods, apostrophes, or hyphens for punctuation.
- The person signing must insert his or her own signature between the forward slash marks, § 1.4(d)(2)(i).
  - **Only the signer can insert his or her own signature:**
    - a secretary, paralegal, etc., is not permitted to sign/ insert another person's signature, *e.g.*, a practitioner's or inventor's signature, and
    - a practitioner is not permitted to sign/insert an inventor's signature or another practitioner's signature.

S-Signature – 5 Requirements (cont.) 37 CFR § 1.4(d)(2)

- The name of the person signing must be printed or typed immediately adjacent (*i.e.,* below, above, or beside) to the S-signature, and be reasonably specific, so the identity of the signer can be readily recognized.

  The name of the person signing may be inserted by someone other than the person signing, but the person signing must personally insert the S-Signature.

  A secretary, paralegal, etc., may type the name of the person signing at any time (*e.g.*, before or after the person signing inserts his or her own signature).

- A registered practitioner may S-sign but his or her registration number is required, either as part of the S-signature, or immediately below or adjacent to the signature.

  For example: ***/John Attorney*** **Reg. #99999/**
  John Attorney

Examples Where S-Signatures Can Be Used

- S-Signatures may be used for correspondence being filed in the Office for patent applications, patents and reexamination proceedings.
- A practitioner creates a document and S-signature signs it on his/her PC. The practitioner can then:
  - Facsimile transmit the document directly from the PC to the Office;
  - File the document via EFS-Web; or
  - Print the document and then facsimile transmit, mail, or hand-carry the document to the Office
- An affidavit under § 1.132 is S-signed by the party making the affidavit, the S-signed affidavit is then:
  - Electronically sent to the practitioner, e.g., via an e-mail. The practitioner can then facsimile transmit, mail or hand-carry the S-signature signed document to the Office, in addition to filing via EFS-Web.
- S-Signatures may not be used for papers submitted to the Office of Enrollment & Discipline § 1.4(e).

Name Requirement for S-Signatures

- There is no requirement that the signer's actual, full or legal name be used.
  - It is strongly suggested that the full name be used for both;
  - The typed or printed name below the signature must be reasonably specific enough so that the identity of the signer can be readily recognized (§ 1.4(d)(2)(iii)(B)).
- Titles may be included as part of the signature.
- Changes in S-signature (different papers or different applications) are not recommended. § 1.4(h)
  - Example: An s-signature that includes the attorney docket number for that application would not be a consistent signature.

Questionable Signatures

- Ratification, confirmation or evidence of authenticity of a signature may be required where the Office has:
  - Reasonable doubt as to its authenticity,
  - Where the signature and typed or printed name do not clearly identify the person signing.
- The failure to follow the S-signature format and content requirements will usually be treated as a bona fide attempt, but will cause the paper to be treated as unsigned with differing results, *e.g.*:
  - Amendments would receive a new 1-month time period
  - § 1.63 declarations would receive a two month time period and a surcharge may be imposed.

Certification Requirements
37 CFR § 1.4(d)(4)

Certification Requirement

A. **<u>For another's signature:</u>** A person submitting a document signed by another under § 1.4(d)(2):

- is obligated to have a reasonable basis to believe that the person whose signature is present on the document actually inserted that signature, and
- should retain evidence of authenticity of the signature.

B. **<u>For your own signature:</u>** The person inserting a signature under § 1.4(d)(2) in a document submitted to the Office certifies that the inserted signature appearing in the document is his or her own signature.

Violations of the signature certifications may result in the imposition of sanctions under §§ 10.18(c) and (d).

Power of Attorney
37 CFR §1.32(b)

37 CFR § 1.32(b) sets forth power of attorney requirements:

- Must be in writing,
- Name one or more representatives in compliance with § 1.32(c),
- Give the representative power to act on behalf of the principal, and
- Be signed by the applicant for patent (§ 1.41(b)) or the assignee of the entire interest of the applicant.

Power of Attorney
37 CFR §1.32(b)

A power of attorney must name as representative either:

- one or more joint inventors;
- up to ten registered patent attorneys or registered patent agents; **or**
- those registered patent practitioners associated with a Customer Number.

Power of Attorney; 37 CFR 1.32(c)

If a power of attorney names more than ten patent practitioners

- Power of attorney must be accompanied by a separate paper indicating which patent practitioners named in the power of attorney, up to 10, are to be recognized by the Office as being of record in application or patent to which the power of attorney is directed.
- If no separate paper, **no** power of attorney will be entered.
- The separate paper can be signed by one of the attorneys or agents of record, by a patent attorney or agent acting in a representative capacity, the assignee, acting pursuant to 37 CFR § 3.73(b), or by all of the applicants.
- The separate paper cannot request that a Customer Number be used instead, only the applicant or assignee can give power of attorney to a Customer Number.
- Effective Date: June 25, 2004

Acting in a Representative Capacity § 1.34

A registered patent attorney or patent agent not of record but acting in a representative capacity must specify his/her:

- Registration number
- Name
- Signature

Acting in a Representative Capacity § 1.34

A person acting in a representative capacity may not sign:

- A power of attorney (37 CFR 1.32(b)(4));
- A document granting access to an application unless
  - an executed declaration has not been filed, and
  - the practitioner was named in the papers accompanying the application papers (37 CFR 1.14(c));
- A change in correspondence address except where an executed oath/declaration has not been filed and the practitioner filed the application (37 CFR 1.33(a)(1));
- A terminal disclaimer (37 CFR 1.321(b)(1)(iv)); or
- A request for an express abandonment without filing a continuing application (37 CFR 1.138(b)).

Request to Withdraw from Representation in a Patent Application

Change in Procedure for Requests to Withdraw from Representation In a Patent Application 1329 OG 99, effective May 12, 2008.

- Office no longer requires at least 30 days between approval of the withdrawal and the later of the expiration date of a time period which can be obtained by a petition and fee for extension of time for reply for a practitioner to withdraw.
- Office will not grant a request to withdraw in a patent.
- Office will not approve request to withdraw from practitioners who acted in a representative capacity (§ 1.34).

Request to Withdraw from Representation in a Patent Application

Office now requires the practitioner(s) to certify that he, she or they have:

1. Given reasonable notice to the client, prior to the expiration of the response period, that practitioner(s) intend to withdraw from employment;
2. Delivered to the client or a duly authorized representative of the client all papers and property (including funds) to which the client is entitled; and
3. Notified the client of any responses that may be due and the time frame within which the client must respond.

Request to Withdraw from Representation in a Patent Application

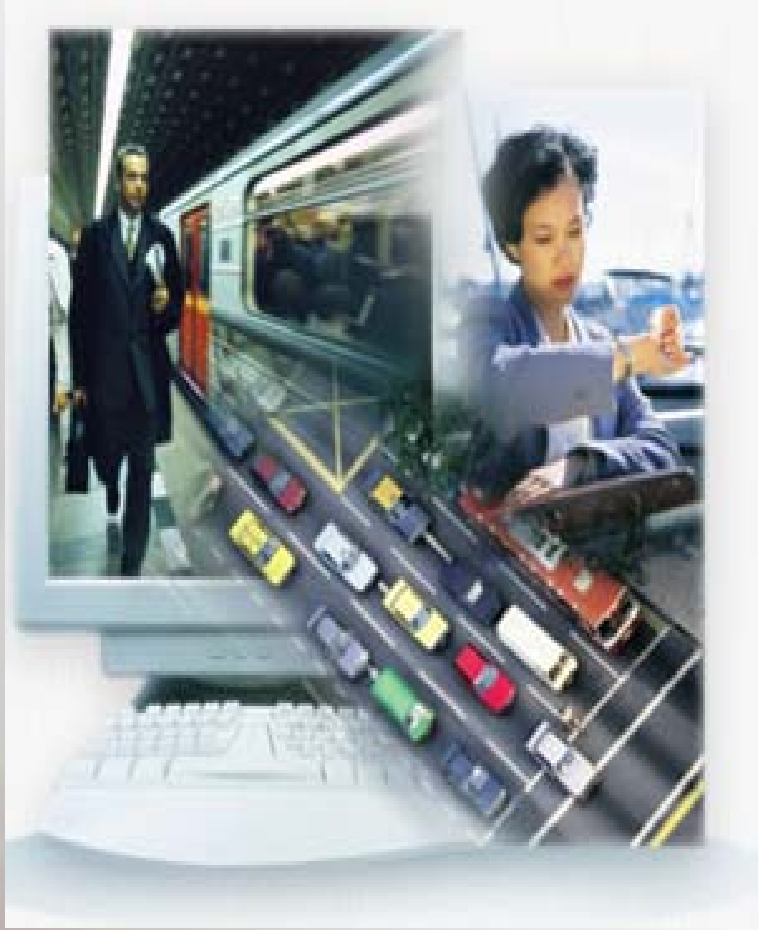
- The Office will no longer accept address changes to a new practitioner, absent a new power of attorney when processing a request to withdraw.
- Correspondence address will be changed to assignee of the entire interest who has properly become of record pursuant to 37 CFR 3.71 or the first named inventor.

Note: **PTO/SB/83 ("Request for Withdrawal as Attorney or Agent and Change of Correspondence Address")**

Initiatives and Programs

- Patents Teleworking and Laptop Programs
- Virtual Art Unit Pilot
- Alternative Examination Products
- Worksharing
- Peer Pilot Review
- Accelerated Examination
- First Action Interview Pilot
- Electronic Filing

Patents Teleworking & Laptop Programs



Over 1,250 examiners participating in the Patents Hoteling Program, since initiated in 2006

- Program allows examiners to work from home 4 days per week with USPTO electronic tools

Over 2300 laptops distributed through Patent Examiner Laptop Program (PELP)

Both Hoteling and Laptop programs show production gains in line with increase in total examination time, as well as improved morale and job satisfaction

Virtual Art Unit Pilot

USPTO Pilot to evaluate the feasibility of establishing "virtual art units"

- Conducted April 2007 - September 2007
- 13 Examiners and 1 SPE at home
  - received full PHP equipment
- 37 examiners remained on USPTO campus
  - received collaboration tools and training
- Random reviews by Office of Patent Quality Assurance
- Surveys administered to all examiners in the art unit; evaluating application of data

Alternative Examination Products

Patent Public Advisory Committee (PPAC) outreach project

- Conducting focus sessions and interviews to obtain insight and feedback
- Patentee / Trade Organization / User Input
  - Wants and Needs for IP Protection
    - Different Levels of Examination / Protection

Worksharing

- Number of initiatives underway to promote examination efficiencies in participating IP offices
- Patent Prosecution Highway (PPH)
  - Full implementation Jan. 4, 2008 – JPO, Jan. 29, 2009 - KIPO
  - Pilot – UK IPO, CIPO, IPAU, EPO, DKPTO, IPOS and DPMA

Peer Review Pilot

- 1 year pilot (began June 15, 2007) for members of the public to submit prior art with commentary, using Internet peer review techniques, in volunteered published applications to a public website (www.peertopatent.org)
  - 75 applications volunteered
  - TC 2100 technology only
  - 10 pieces of prior art max per application (avg. was 4)
- Pilot extended 1 year to include Business Methods – Class 705
  - Encourage more participation
  - Technology heavy with Non-patent literature

Accelerated Examination

- Change in practice effective August 25, 2006
- Opportunity for final determination in 12 months
- Participation requires:
  - Applicants provide greater information up front – pre-examination search and accelerated examination support document;
  - file application using electronic fling system;
  - agree to interviews
  - Limited number of claims

Accelerated Examination Current Statistics

- As of Feb. ’09:
  - 690 applications allowed
    - On average, 197 days to complete prosecution
    - Minimum number of days to complete prosecution: 18
- 193 patents have issued (8/19/08)
- Participants’ response & comments positive
  - Not only faster, but high quality

First Action Interview Pilot

- Applicant requests to participate, as of July 5, 2008, 279 applicants have joined the pilot
- Application is NOT taken out of turn
- "Preliminary office action" is prepared and mailed to applicant – condensed version of typical first action on the merits
- After interview applicant receives copy of action or allowance with entry of proposed amendment
- Piloted in two workgroups of TC 2100

Electronic filing

New EFS-Web system launched
March 2006

- § allows PDF-based submissions
- § replaced XML-based system

2005 result: 2.2% of applications filed electronically

2006 result: 14.3% of applications filed electronically

2007 result: nearly 50% of applications filed received through EFS-Web; over 1,000,000 (total) follow-on papers and new applications received

2008 result: 72.1% of applications filed electronically

2009 result: 81% of applications filed electronically, so far

Electronic filing

- Safe, Simple, Secure
- Many corporations, law firms, and independent inventors moving to 100% electronic filing for new applications and follow-on papers.

Recent Notices and Pre-OG Notices are posted at: http://www.uspto.gov/web/offices/pac/dapp/ogsheet.html

United States Patent and Trademark Office PATENTS

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Patents > Office of the Deputy Commissioner for Patent Examination Policy > Office of Patent Legal Administration > Recent Patent-Related Notices

TITLE* * active hyperlinks in this column retrieve USPTO documents posted prior to publication in the OG or Fed. Reg.	OG CITE	OG DATE	FR CITE	FR DATE
Special Mail Stops for Patent Mail (posted 10Mar2005) *[The changes to this notice pertain to the elimination of filing an expedited Design application by hand-delivery to the Design Group Director's Office, move of Licensing and Review on **April 1, 2005**; the elimination of Box or Mail Stop 4 in 37 CFR 150.6 and its replacement with Mail Stop Congressional Relations, and the move of the Office of Finance to **Suite 807**.]*		5APR2005		

Further Information

USPTO Useful Web Links - http://www.uspto.gov

Helpful Web Pages:

- Notices, Recent Patent-Related – a very current list of all Federal Register, Official Gazette and pre-Official Gazette notices, and certain Office memoranda: http://www.uspto.gov/web/offices/pac/dapp/ogsheet.html
- Forms Page – current USPTO forms available for use by the Public: http://www.uspto.gov/web/forms/index.html
- Manual of Patent Examining Procedure (MPEP): http://www.uspto.gov/web/offices/pac/mpep/mpep.htm

USPTO Useful Web Links (cont'd)

- Mailing Addresses and Mail Stops: http://www.uspto.gov/web/offices/com/sol/og/patboxs.htm
- Facsimile Numbers: http://www.uspto.gov/web/offices/com/sol/og/2005/week42/patcorr.htm
- USPTO Glossary: http://www.uspto.gov/main/glossary/index.html

The Written Description Requirement of 35 U.S.C. 112, first paragraph: Chemical Practice

TC 1600 Training

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Quality Assurance Specialist

35 U.S.C. 112, first paragraph

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

Written Description: Applications

- Utility patent applications:
  - New claims and amended claims.
  - Claims asserting domestic benefit or foreign priority.
  - Original claims. *The Regents of the University of California v. Eli Lilly*, 119 F.3d 1559, 43 USPQ2d 1398, (Fed. Cir. 1997).

Early Written Description (Domestic Benefit)

***In re Ruschig*, 379 F.2d 990, 154 USPQ 118 (CCPA 1967).**

- **Support required in originally-filed generic disclosure for later-presented or amended species claims.**
- **The *Ruschig* court employed the famous metaphor to indicate that a sufficient disclosure is one that marks a trail through the woods by supplying blaze marks on the trees. *Ruschig,* 154 USPQ at 122.**

See also: MPEP 2163 IA (Original Claims).

New or Amended Claims, or Claims Asserting Entitlement to Earlier Filing Date

- **Each claim limitation must be expressly, implicitly, or inherently supported in the originally filed disclosure.**

See also: MPEP 2163 IB (New or Amended Claims).

Inherent Support

Spero v. Reingold, **377 F.2d 652, 153 U.S.P.Q. 726 (CCPA 1967):**

- **Inherency provided an adequate written description of a specific 6-ß-methyl configuration of a compound, even in the absence of a specific naming of the compound or a disclosure of identifying characteristics, where:**

1. **It was known to chemists that there were only two possible configurations (6-ß-methyl and 6-α-methyl); and**
2. **The application procedure worked to produce only one steric configuration (the 6-ß-methyl).**

- **See also: *Kennecott v. Kyocera*, 835 F.2d 1419, 5 USPQ2d 1194 (Fed. Cir. 1987) (Disclosure in a subsequent patent application of an inherent property i.e., equiaxed microstructure of a ceramic product does not deprive that product of the benefit of an earlier filing date).**

USPTO Written Description Guidelines, Examples, and Notices

- **Written Description Guidelines (66 FR 1099 (Jan. 5, 2001); 1242 O.G. 168 (Jan. 30, 2001)**
  - **http://www.uspto.gov/web/menu/current.html#register**
  - **First posted December 27, 1999**
- **Training Materials**
  - **Revision I of the Written Description Training materials, posted 4/11/08 that supercede and replace the 1999 training materials at: http://www.uspto.gov/web/menu/written.pdf dated 3-25-08.**
  - **MPEP 2163**

Written Description - General Principles

- **Basic inquiry: Would one skilled in the art reasonably conclude that the inventor had possession of the claimed invention at the time the application was filed?**
  - ***Regents of the University of California v. Eli Lilly & Co.*, 119 F.3d 1559, 1566-67, 43 USPQ2d 1398, 1404-05 (Fed. Cir. 1997); *Hyatt v. Boone*, 146 F.3d 1348, 1354, 47 USPQ2d 1128, 1132 (Fed. Cir. 1998); *MPEP 2106*.**

- **Written description requirement is separate and distinct from the enablement requirement.**
  - ***See, e.g., Vas-Cath, Inc. v. Mahurkar, 935 F.2d 1555, 1560, 19 USPQ2d 1111, 1114 (Fed. Cir. 1991). See also Univ. of Rochester v. G.D. Searle & Co., 358 F.3d 916, 920-23, 69 USPQ2d 1886, 1890-93 (Fed. Cir. 2004) (discussing history and purpose of the written description requirement); In re Curtis, 354 F.3d 1347, 1357, 69 USPQ2d 1274, 1282 (Fed. Cir. 2004) ("conclusive evidence of a claim's enablement is not equally conclusive of that claim's satisfactory written description"); MPEP 2163.***

Written Description – Basics of Examiner's Analysis

- **Determine the scope of each claim as a whole**
  - **Broadest reasonable interpretation in light of and consistent with written description**
    - ***In re Morris*, 127 F.3d 1048, 44 USPQ2d 1023 (Fed. Cir. 1997); and MPEP 2163.**
  - **Consider the full scope of the claim**

Written Description –Basics of Examiner's Analysis (cont.)

- **Review entire application to understand how the applicant provides support for the claimed invention**
  - **Review includes consideration for each element and/or step claimed.**
  - **Review includes comparing the claim scope with the scope of the disclosure.**

Written Description – Basics of Examiner's Analysis (cont.)

- Factors to consider when analyzing claims for compliance with the written description requirement **:**
  a. **Actual reduction to practice**
  b. **Disclosure of drawings or structural chemical formulas**
  c. **Sufficient relevant identifying characteristics**
  d. **Method of making the claimed invention**
  e. **Level of skill and knowledge in the art**
  f. **Predictability in the art.**

See MPEP 2163 II. A. (a).

Written Description – Basics of Examiner's Analysis (cont.)

a. Actual reduction to practice

- Does the specification show any embodiments that meet all the limitations of the claim reduced to practice?
- *Actual Reduction to practice not required to meet written description cf.: Amgen Inc. v. Chugai Pharmaceutical Co., 927 F.2d 1200, 18 USPQ2d 1016 (Fed. Cir. 1991).*
- *Actual Reduction to practice of a subset of embodiments may or may not be sufficient to show possession of a genus.*

b. Disclosure of drawings or structural chemical formulas

- An applicant may show possession of an invention by disclosure of drawings or structural chemical formulas that are sufficiently detailed to show that applicant was in possession of the claimed invention as a whole.

  - *See, e.g., Vas-Cath, 935 F.2d at 1565, 19 USPQ2d at 1118; In re Wolfensperger, 302 F.2d 950, 133 USPQ 537 (CCPA 1962); Autogiro Co. of America v. United States, 384 F.2d 391, 398, 155 USPQ 697, 703 (Ct. Cl. 1967); Eli Lilly, 119 F.3d at 1568, 43 USPQ2d at 1406; MPEP 2163.*

Written Description –Basics of Examiner's Analysis (cont.)

c. **Sufficient relevant identifying characteristics:**
   - i. **Complete structure**
   - ii. **Partial structure**
   - iii. **Physical and/or chemical properties**
   - iv. **Functional characteristics when coupled with correlation between structure and function**

Enzo Biochem, Inc. v. Gen-Probe, Inc., **323 F.3d 956, 964, 63 USPQ2d 1609, 1613*;***

(Fed. Cir. 2002); MPEP 2163

Written Description – Basics of Examiner's Analysis (cont.)

d. **Method of making the claimed invention**

e. **Level of skill and knowledge in the art**

- **What is conventional or well known to one skilled in the art need not be disclosed in detail. *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 19 USPQ2d 1111 (Fed. Cir. 1991).**
- **Prior art, IDS references and Applicant Declarations may be useful to establish the level of skill and knowledge in the art.**

f. **Predictability in the art**

Written Description – Basics of Examiner's Analysis for Genus Claims

- **WD for claimed genus may be satisfied through sufficient description of a representative number of species**
  - **inverse function of the skill and knowledge in the art.**
  - **depends on whether one of skill in the art would recognize necessary common attributes or features possessed by the members of the genus.**
  - **generally, in an unpredictable art, adequate WD of a genus which embraces widely variant species cannot be achieved by disclosing only one species within the genus.**
- ***See Enzo Biochem,* 323 F.3d 956,966, 63 USPQ2d 1609,1615*; Noelle v. Lederman,* 355 F.3d 1343, 1350, 69 USPQ2d 1508, 1514 (Fed. Cir. 2004); *Regents of the University of California v.Eli Lilly,* 119 F.3d at 1568, 43 USPQ2d at 1406 (Fed. Cir. 1997) .**

Burden on the Examiner with Regard to the Written Description Requirement

- **Description as filed presumed adequate**
- **No *per se* rules**
- **Unsupported allegation of unpredictability in the art is insufficient**
- **Need reasonable basis to challenge**
  - **Evidence**
  - **Technical reasoning**

See MPEP 2163.04

Level of Skill and Knowledge in the Art: Predictability

- ***In re Herschler*, 591 F.2d 693 (CCPA 1979).**
- **Claim: A method of enhancing the penetration into and across an external membrane barrier of a human or animal subject of a physiologically active steroidal agent capable of eliciting a physiological effect upon topical application thereof, which comprises the concurrent topical administration to the external membrane of an amount of said steroidal agent effective to produce the desired physiological effect and an amount of DMSO sufficient to effectively enhance penetration of said steroidal agent to achieve the desired physiological effect (emphasis added).**

In re Herschler : Issue

- **Issue: For purposes of 35 U.S.C. 120 benefit, did the prior application provide sufficient WD for the claimed invention as a whole, including the limitation requiring "an amount of DMSO sufficient to effectively enhance penetration of said steroidal agent to achieve the desired physiological effect"?**

In re Herschler: Parent Disclosure

- Claim: A method of enhancing the penetration into and across an external membrane barrier of a human or animal subject of a physiologically active steroidal agent capable of eliciting a physiological effect upon topical application thereof, which comprises the concurrent topical administration to the external membrane of an amount of said steroidal agent effective to produce the desired physiological effect and an amount of DMSO sufficient to effectively enhance penetration of said steroidal agent to achieve the desired physiological effect (emphasis added).
- **Exemplified making topical compositions (ointment and lotion) of DMSO and a corticosteroid; and demonstrated penetration to relieve inflammation in a patient.**
- **Disclosed DMSO, Glucocorticosteroids(20-keto steroid structure) and a corticosteroid (dexamethasone 21-phosphate).**

In re Herschler: Analysis

- Claim: A method of enhancing the penetration into and across an external membrane barrier of a human or animal subject of a physiologically active steroidal agent capable of eliciting a physiological effect upon topical application thereof, which comprises the concurrent topical administration to the external membrane of an amount of said steroidal agent effective to produce the desired physiological effect and an amount of DMSO sufficient to effectively enhance penetration of said steroidal agent to achieve the desired physiological effect (emphasis added).
- **Exemplified making and using DMSO in steroid compositions to enhance topical delivery.**
- **No structure / function correlation need be shown since only DMSO is claimed for its functional properties.**
- **Cortico-steroids are a recognized subclass of "physiologically active steroidal agents" with predictable art-recognized functions.**

In re Herschler: Conclusion

- **Held: prior disclosure of a corticosteroid in DMSO was sufficient to support claims drawn to a method of using a mixture of a "physiologically active steroid" and DMSO because "use of known chemical compounds in a manner auxiliary to the invention must have a corresponding written description only so specific as to lead one having ordinary skill in the art to that class of compounds. … Occasionally, a functional recitation of those known compounds in the specification may be sufficient as that description.". MPEP 2163 IBII.A.**

In re Herschler: Conclusion (cont.)

- **Note however, that: "[C]ases … such as *In re Herschler*, 591 F.2d 693 (C.C.P.A. 1979) … indicate, as this Court has recognized, that it is not always necessary to set forth exact chemical formulas to satisfy § 112, ¶ 1, but they do not hold that a functional description of a chemical compound is necessarily sufficient. *University of Rochester v. G.D. Searle & Co., Inc*. 249 F. Supp.2d 216, 227 (W.D.N.Y., 2003).**
- **Adequate WD is determined on a case-by-case basis.**

Level of Skill and Knowledge in the Art: Unpredictability

- ***In re Curtis 354 F. 3d 1347; 69 USPQ 2d 1274 (Fed. Cir. 2004):***

Claim: A dental cleaning floss comprising at least one polytetrafluoroethylene (PTFE) strand that has been expanded by stretching under conditions to increase the tensile strength thereof, said floss having a coating of at least one material capable of increasing the coefficient of friction, wherein said dental floss has a denier of about 500 to 1500 and a coefficient of friction of about 0.08 to about 0.25.

- **Issue: Entitlement of above claim in child case to 35 U.S.C. 120 benefit of the filing date of the parent case when the disclosure in the parent was limited to floss coated with microcrystalline wax (MCW).**

In re Curtis: Parent Specification

Claim: A dental cleaning floss comprising at least one polytetrafluoroethylene (PTFE) strand that has been expanded by stretching under conditions to increase the tensile strength thereof, said floss having a coating of at least one material capable of increasing the coefficient of friction, wherein said dental floss has a denier of about 500 to 1500 and a coefficient of friction of about 0.08 to about 0.25.

- **Specification compared the coefficient of friction (COF) of MCW coated PTFE flosses to leading brands of commercially marketed dental floss and expanded PTFE floss having no coating.**
- **Found that from amongst different waxes, microcrystalline wax (MCW) adheres to Expanded PTFE and unexpectedly results in a COF sufficiently high enough to permit the user to securely grasp the floss, but generally not so high as that of the prior art which would not easily slide between the teeth without breaking.**

In re Curtis: Analysis

Claim: A dental cleaning floss comprising at least one polytetrafluoroethylene (PTFE) strand that has been expanded by stretching under conditions to increase the tensile strength thereof, said floss having a coating of at least one material capable of increasing the coefficient of friction, wherein said dental floss has a denier of about 500 to 1500 and a coefficient of friction of about 0.08 to about 0.25.

- **MCW was the only PTFE floss coating actually reduced to practice.**
- **Although other waxes were disclosed, there was no disclosure of drawings, partial or complete structure or chemical formulas of any other coating for PTFE floss.**
- **No known or disclosed correlation between non-wax compound structure and the ability to function as a friction enhancing coating.**
- **Lack of prior art friction coating materials capable of possessing COF of MCW resulted in unexpected property.**

In re Curtis: Conclusion

- **MCW was not representative of the genus of "friction enhancing coatings", especially when MCW properties were unexpected.**
- **Conclude: "parent" application does not provide WD for later-claimed genus of friction enhancing PTFE dental floss coatings since there was only one disclosed embodiment (MCW) that unpredictably adhered to PTFE.**

Level of Skill and Knowledge In the Art : Summary

- **Generally, a well-established subclass of compounds of similar structure with predictable properties should not be the basis of a WD rejection:**

- **Steroids (*In re Herschler*):**

  "[S]teroids, when considered as a class of compounds carried through a layer of skin by DMSO, appear on the record to be chemically quite similar. The diversity of exemplified materials "potentiated" by DMSO in the great-grandparent application, is much broader than the diversity of steroid compounds shown contemporaneously in the art. In this instance, we conclude that one having ordinary skill in the art would have found the use of the subgenus of steroids to be apparent in the written description of the great-grandparent application". *In re Herschler,* 591 F.2d 693, 701(CCPA 1979).

Level of Skill and Knowledge In the Art : Summary (Cont.)

- **However, a subclass of compounds whose members unpredictably vary in structure and/or properties may raise WD concerns:**

- **PTFE dental floss coatings (*In re Curtis*):**

  "A patentee will not be deemed to have invented species sufficient to constitute the genus by virtue of having disclosed a single species when … the evidence indicates ordinary artisans could not predict the operability in the invention of any species other than the one disclosed." *In re Curtis, 354 F.3d 1347, 1358, 69 USPQ2d 1274, 1282 (Fed. Cir. 2004).*

- **See MPEP 2163 IBII.A.**

WD: Single Compound: Original Claim

- **Satisfies WD when the compound claim corresponds to an actual reduction to practice of the compound in the specification by, e.g., use of a structure or detailed drawing of a readily synthesized compound.**
- **However, compound claims may, in some instances, further satisfy WD by use of one or more disclosed "identifying characteristics":**

1. **Partial structure e.g., Partial Protein Structure: Example 5, Revised WD Training materials;**
2. **Physical and/or chemical properties**
3. **Functional Characteristics;**
4. **Structure/Function correlation**
5. **Method of Making.**

WD: Single Compound: Partial Protein Structure

- ***Partial Protein Structure: Example 5, Revision I of the Written Description Training materials.***
  - **Claim. An isolated protein comprising Protein A, wherein said Protein A**
    - **includes the amino acid sequence of SEQ ID NO: 1 in the N-terminal portion of the protein,**
    - **has the same ability to bind to and activate Protein X as Protein A from human urine,**
    - **and wherein said Protein A is purified by subjecting a crude protein recovered from a dialyzed concentrate of human urine to affinity chromatography on a column of immobilized Protein X, and elutes from a reversed-phase HPLC column as a single peak in a fraction corresponding to about 31% acetonitrile and shows a molecular weight of about 22 kDa when measured by SDS-PAGE under reducing conditions.**

Partial Protein Example: Disclosure

- The specification discloses partial structure, i.e., SEQ ID: 1.
- Other relevant identifying characteristics are disclosed
  - ability to bind and activate Protein X,
  - molecular weight and
  - concentration of acetonitrile at which Protein A will elute from a reverse phase HPLC column.
- The specification also discloses a method for isolating Protein A from human urine and a working example demonstrating successful isolation.

Partial Protein Example: Conclusion

- Those of skill in the art of isolating proteins would recognize the inventor to be in possession of the claimed protein at time of filing based on
  - the identifying characteristics and
  - disclosed method of isolating.

- The specification satisfies the WD requirement with respect to the full scope of claim 1.

Markush Original Claims (synthesizable, without a claimed function)

- **Original claims that define compounds by "structure or formula" such as:**

  X-Phenyl-CH2-CH-NH-C(O)-Y, wherein

  X is selected from the group consisting of ….; and

  Y is selected from the group consisting of … .

Markush Original Claims

***Generally*, for Markush Claims Defined by Structure or Formula:**

- **Possession may be shown by a clear depiction of the invention … in structural chemical formulas which permit a person skilled in the art to clearly recognize that applicant had possession of the claimed invention. MPEP 2163.**
- **Original claims constitute their own description, *In re Koller*, 613 F.2d 819, 204 USPQ 702 (CCPA 1980); MPEP 2163.**

Genus Claims: WD

- **WD may exist for a genus whose members are generally known or are recognizable based:**

- **on a generic formula (*In re Gardner*, 475 F.2d 1389, 177 USPQ 396 (CCPA 1973)) or**

- **on a known or disclosed correlation between structure and function.**

- **WD for claimed genus may also be satisfied through sufficient description of a representative number of species.**

See MPEP 2163 IA.

- **Note: a claim may meet WD but not be enabled.**

WD: Example 1: Derivatives and Analogs (Claim)

- ***Based on the facts of Coolidge and Ehlers v. Efendic (BPAI: Patent Interference No. 105,457: May 16, 2008).***

- **Claim: A method of treating stroke, comprising administering an effective amount of a compound selected from the group consisting of GLP-1, GLP-1 analogs, GLP-1 derivatives, and pharmaceutically–acceptable salts thereof, to a patient in need thereof.**
- **GLP-1 (Glucagon-like Peptide-1).**

Ex.1: Derivatives and Analogs (Specification)

- **Claim: A method of treating stroke, comprising administering an effective amount of a compound selected from the group consisting of GLP-1, GLP-1 analogs, GLP-1 derivatives, and pharmaceutically–acceptable salts thereof, to a patient in need thereof.**

- **Specification discloses:**
  - **that the risk of stroke is elevated in diabetic and hyperglycemic patients; and that**
  - **GLP-1 (Glucagon-like Peptide-1) lowers blood glucose levels in people with elevated blood glucose levels.**

- **Specification exemplifies:**
  - **GLP-1(7-36) amide infusion in NIDDM patients was better than injected insulin at lowering blood glucose levels and controlling post-prandial glucose levels.**

Ex. 1: Derivatives and Analogs (Specification Cont.)

- **Claim: A method of treating stroke, comprising administering an effective amount of a compound selected from the group consisting of GLP-1, GLP-1 analogs, GLP-1 derivatives, and pharmaceutically–acceptable salts thereof, to a patient in need thereof.**

  - **"GLP- 1" means GLP- 1 (7-37) with well known sequence:**

NH_2-His^{7}-Ala-Glu-Gly^{10}-Thr-Phe-Thr-Ser-Asp^{15}-Val-Ser-Ser-Tyr-Leu^{20}-Glu-Gly-Gln-Ala-Ala^{25}-Lys-Glu-Phe-Ile-Ala^{30}-Trp-Leu-Val-Lys-Gly^{35}-Arg-Gly^{37}-COOH

  - **A "GLP-1 analog" is a molecule having a modification including one or more amino acid substitutions, deletions, inversions, or additions when compared with-GLP-1.**

  - **A "GLP-1 derivative" is a molecule having the amino acid sequence of GLP-1 or of a GLP-1 analog but additionally having at least one chemical modification of one or more of its amino acid side groups, alpha-carbon atoms, terminal amino group, or terminal carboxylic acid group. Chemical modification includes adding chemical moieties, creating new bonds, and removing chemical moieties.**

Ex. 1: Derivatives and Analogs (Specification Cont.)

- **Claim: A method of treating stroke, comprising administering an effective amount of a compound selected from the group consisting of GLP-1, GLP-1 analogs, GLP-1 derivatives, and pharmaceutically–acceptable salts thereof, to a patient in need thereof.**
- **GLP-1 analogs known in the art include, for example, GLP-1(7-34) and GLP-1 (7-35), GLP-1 (7-36), Val.sup.8-GLP-1(7-37), Gln.sup.9-LP-1 (7-37), D-Gln.sup.9-GLP-1(7-37), Thr.sup.16-Lys.sup.18-GLP-1(7-37), and Lys.sup.18-GLP-1(7-37). Preferred GLP-1 analogs are GLP-1(7-34) and GLP-1(7-35), which are disclosed in U.S. Pat. No. 5,118,666, and also GLP-1(7-36). Other GLP-1 analogs are disclosed in U.S. Pat. No. 5,545,618.**
- **GLP-1 analogs, derivatives, variants, precursors and homologues are all suitable for the practice of the invention as long as the active fragment that effects reduced mortality or morbidity after stroke is included.**

Ex. 1: Derivatives and Analogs (Analysis)

- Claim: A method of treating stroke, comprising administering an effective amount of a compound selected from the group consisting of GLP-1, GLP-1 analogs, GLP-1 derivatives, and pharmaceutically–acceptable salts thereof, to a patient in need thereof.
- **Exemplified metabolic control and reduced blood glucose levels with GLP-1(7-36) amide in NIDDM patients (Actual Reduction To Practice of a GLP-1 analog / derivative species in a stroke susceptible patient).**
- **Although specification discloses structural formulas for specific GLP-1 analogs and derivatives, the claim is not so limited, but encompasses millions of compounds.**
- **The active fragment definition (i.e., that effects reduced mortality or morbidity after stroke) is functional in nature and there is no art-recognized correlation between a defined active fragment function with a particular chemical structure.**

Ex. 1: Derivatives and Analogs (Analysis)

- **Claim: A method of treating stroke, comprising administering an effective amount of a compound selected from the group consisting of GLP-1, GLP-1 analogs, GLP-1 derivatives, and pharmaceutically–acceptable salts thereof, to a patient in need thereof.**
- **Although there may be more than one active GLP-1 fragment, neither the specification, nor the prior art have identified any active fragments.**
- **Although one could test potential active fragments for insulinotropic activity, the correlation between insulinotropic activity and reducing mortality and morbidity after stroke would need to be determined.**

Ex. 1: Derivatives and Analogs: Conclusion

- **The achievement of reduced blood glucose levels in patients using one GLP-1 analog/derivative compound would not be deemed by one of skill in the art to be representative of the claimed scope of GLP-1 analogs/derivative useful for treating stroke.**
- **Claimed treatment of stroke administering GLP-1 analogs and derivatives lacked sufficient written description under 35 U.S.C. § 112, 1st paragraph.**

WD: Example 2: Drug Release Tablet (Claim)

- ***Based on the facts of Ex parte Oberegger et al. (BPAI: Appeal 2008-0304: July 31, 2008)*.**
- **Claim: A modified release tablet suitable for use in once-daily oral administration of Drug X wherein said modified release tablet provides a blood C_{max} for Drug X of about 60ng/ml at between 3 and 8 hours post administration and an area under the plasma drug concentration-time curve ($AUC_{0\text{-}infinity}$) of about 800ng-hr/ml to about 2850ng-hr/ml.**

Ex. 2: Drug Release Tablet (Specification)

- **Claim: A modified release tablet suitable for use in once-daily oral administration of Drug X wherein said modified release tablet provides a blood C_{max} for Drug X of about 60ng/ml at between 3 and 8 hours post administration and an area under the plasma drug concentration-time curve ($AUC_{0\text{-}infinity}$) of about 800ng-hr/ml to about 2850ng-hr/ml.**

- **6 modified release tablets are exemplified in the specification, each characterized by:**
  - **a core containing Drug X plus a binder and excipient**
  - **a semi-permeable coating comprising water-permeable film-forming polymer A, a plasticizer and water-soluble polymer B**
  - **a surrounding moisture barrier coat comprising acrylic polymer C plus permeation enhancer A.**

Ex.2: Drug Release Tablet (Specification Cont.)

- **Claim: A modified release tablet suitable for use in once-daily oral administration of Drug X wherein said modified release tablet provides a blood C_{max} for Drug X of about 60ng/ml at between 3 and 8 hours post administration and an area under the plasma drug concentration-time curve ($AUC_{0\text{-}infinity}$) of about 800ng-hr/ml to about 2850ng-hr/ml.**
- **All six exemplified tablets contain the same ingredients, in the same layers, differing only in the amount of polymer present.**
- **The specification contemplates that an extensive number of alternative ingredients may be used in varying amounts to form the modified release tablet, with instructions for testing for bioavailability metrics.**

Ex. 2: Drug Release Tablet (Analysis)

- **Claim: A modified release tablet suitable for use in once-daily oral administration of Drug X wherein said modified release tablet provides a blood C_{max} for Drug X of about 60ng/ml at between 3 and 8 hours post administration and an area under the plasma drug concentration-time curve ($AUC_{0\text{-}infinity}$) of about 800ng-hr/ml to about 2850ng-hr/ml.**
- **The claim is drawn to a genus of tablets capable of achieving the recited C_{max}, and AUC metrics.**
- **The claim is not limited to any specific tablet structure.**
- **There may be substantial variability among the species of tablets encompassed including variability in tablet design structure and ingredients.**
- **Actual reduction to practice and the complete structure of 6 species of tablets are disclosed.**
- **No other tablet structures or designs are disclosed.**

Ex. 2: Drug Release Tablet (Analysis Cont.)

- **Claim: A modified release tablet suitable for use in once-daily oral administration of Drug X wherein said modified release tablet provides a blood C_{max} for Drug X of about 60ng/ml at between 3 and 8 hours post administration and an area under the plasma drug concentration-time curve ($AUC_{0\text{-infinity}}$) of about 800ng-hr/ml to about 2850ng-hr/ml.**
- **The only disclosed structures meeting the functional requirements have defined features in common, i.e., a core and two layers of specific polymers and ingredients.**
- **There is no correlation between any other tablet structure and the required bioavailability metrics.**
- **The specification describes a method of testing tablets for the required bioavailability metrics.**
- **No information regarding what other structures would likely result in the required bioavailability metrics.**

Ex. 2: Drug Release Tablet (Analysis Cont.)

- **Claim: A modified release tablet suitable for use in once-daily oral administration of Drug X wherein said modified release tablet provides a blood C_{max} for Drug X of about 60ng/ml at between 3 and 8 hours post administration and an area under the plasma drug concentration-time curve ($AUC_{0\text{-}infinity}$) of about 800ng-hr/ml to about 2850ng-hr/ml.**
- **There are no tablets known in the art with the required bioavailability metrics.**
- **It is known in the art that polymer selection greatly affects release of drugs from drug delivery vehicles, including core tablets.**
- **There is no guidance in the art directed to which tablet structures/ingredients combination predictably correlate with the required bioavailability metrics for Drug X.**

Ex. 2: Drug Release Tablet (Conclusion)

- **One of skill in the art would have concluded that applicant was in possession of once per day modified release tablets with the common structural features of**
  - **a core containing Drug X plus a binder and excipient**
  - **a semi-permeable coating comprising water-permeable film-forming polymer A, a plasticizer and water-soluble polymer B**
  - **a moisture barrier comprising acrylic polymer C plus permeation enhancer A.**
- **One of skill in the art would have concluded that applicant was <u>not in possession</u> of the claimed genus of any tablet having the specified bioavailability metrics.**

Ex. 2: Drug Release Tablet (Conclusion cont.)

- **If the specification in this fact pattern had a diversity of examples showing different polymers or polymer combinations which give rise to the same release profile, written description might be satisfied.**
- **Written description for a claimed genus may be satisfied through sufficient description of a representative number of species.**

Questions

Bennett Celsa

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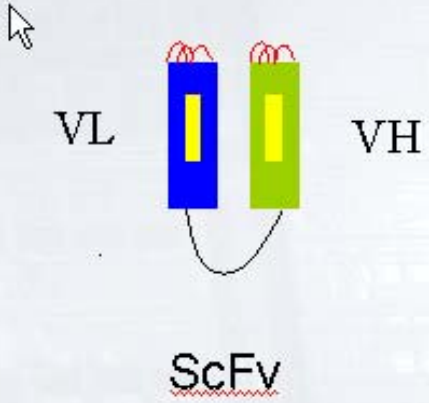
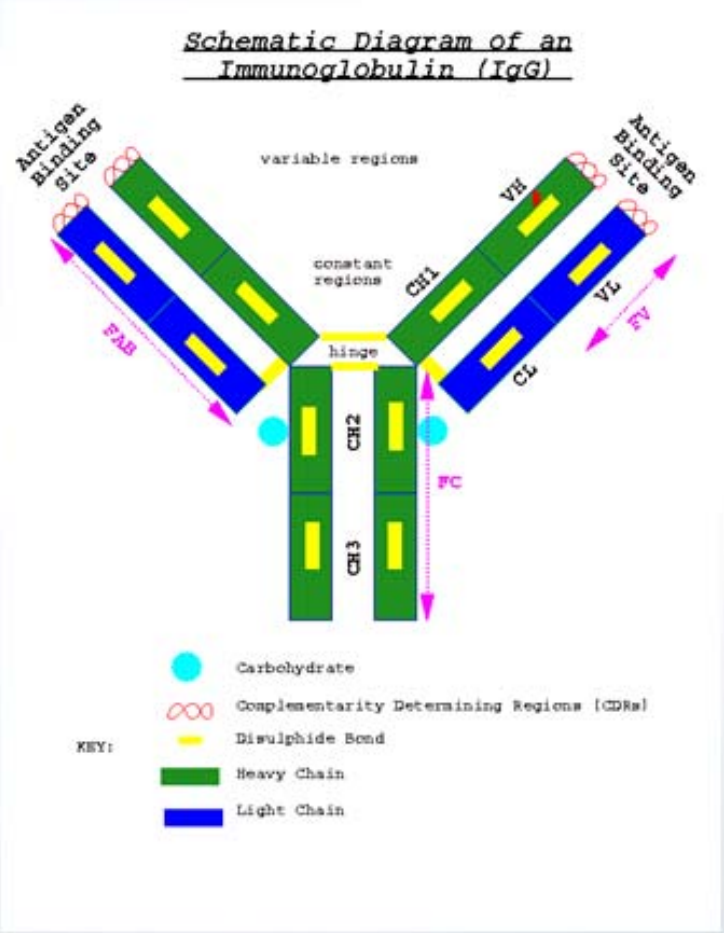
Written Description:
Antibodies

Bennett Celsa
TC 1600 QAS

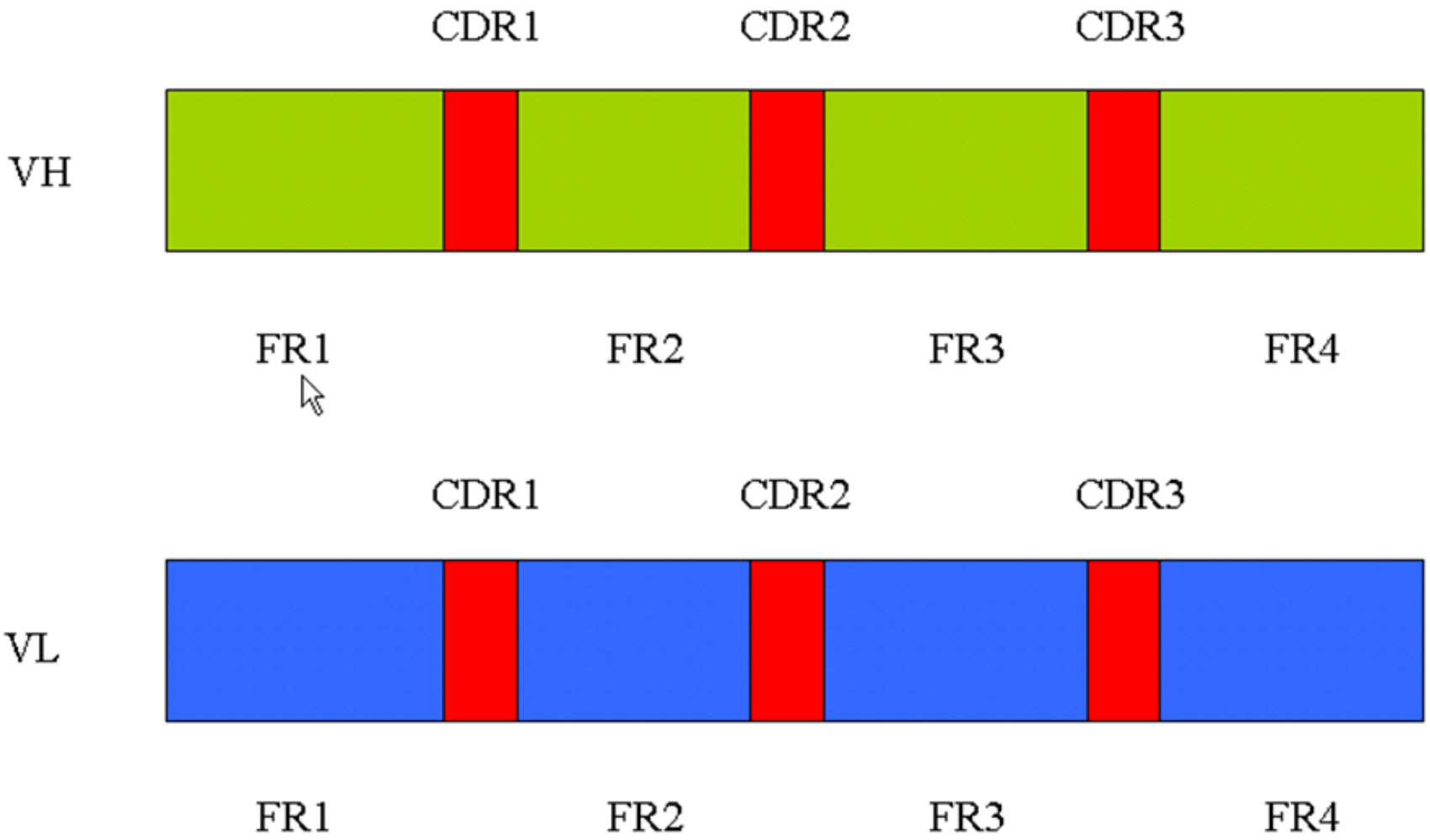
Antibody Structure



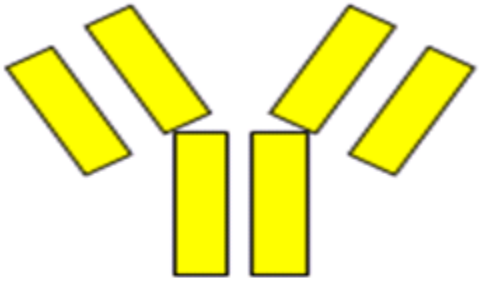


Adapted from people.cryst.bbk.ac.uk/~ubcg07s/gifs/igG.gif

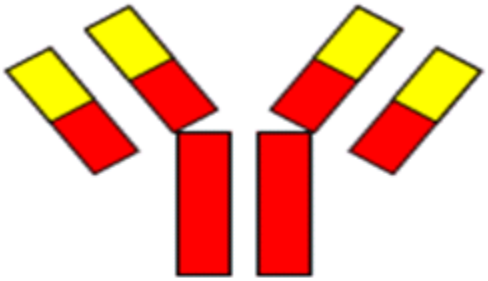
Antibody Variable Domains



Humanization of Antibodies



Mouse



Chimaeric

Humanized

Human

The W.D. Guidelines

- MPEP 2163: W.D. guidelines for complying with the written description requirement of 35 U.S.C. 112, 1st Para. that the "specification shall contain a written description of the invention. … ".

- This requirement is separate and distinct from the enablement requirement.

- Training Materials

  Written Description Training materials, Revision I , March 25, 2008 (available at http://www.uspto.gov/web/menu/written.pdf) (hereinafter Revised Training Materials)

The W.D. Requirement

- "The 'written description' requirement implements the principle that a patent must describe the technology that is sought to be patented; the requirement serves both to satisfy the inventor's obligation to disclose the technologic knowledge upon which the patent is based, and to demonstrate that the patentee was in possession of the invention that is claimed." *Capon v. Eshar*, 418 F.3d 1349, 1357, 76 USPQ2d 1078, 1084 (Fed. Cir. 2005); MPEP 2163.

Written Description – Basics of Examiner's Analysis

- **Determine the scope of each claim as a whole**
  - **Broadest reasonable interpretation in light of and consistent with written description**
    - ***In re Morris*, 127 F.3d 1048, 44 USPQ2d 1023 (Fed. Cir. 1997); and MPEP 2163.**
  - **Consider the full scope of the claim**

Written Description –Basics of Examiner's Analysis (cont.)

- **Review entire application to understand how the applicant provides support for the claimed invention**
  - **Review includes consideration for each element and/or step claimed.**
  - **Review includes comparing the claim scope with the scope of the disclosure.**

- **The determination of compliance with WD is decided on a case-by-case basis.**

Considerations For Determining Compliance with WD

- Evaluate the following:

  a. Actual reduction to practice (e.g. Examples)

  b. Disclosure of drawings or structural chemical formulas

  c. Sufficient relevant identifying characteristics

  - Complete structure
  - Partial structure
  - Physical and/or chemical properties
  - Functional Characteristics when coupled with a known or disclosed correlation between function and structure

  d. Method of making the claimed invention

  e. Level of skill and knowledge in the art

  f. Predictability in the art.

See MPEP 2163(II)(A)(3) and page 1 of the "Revised Training Materials".

Written Description – Basics of Examiner's Analysis for Genus Claims

- **WD for claimed genus may be satisfied through sufficient description of a representative number of species**
  - **inverse function of the skill and knowledge in the art.**
  - **depends on whether one of skill in the art would recognize necessary common attributes or features possessed by the members of the genus.**
  - **generally, in an unpredictable art, adequate written description of a genus which embraces widely variant species cannot be achieved by disclosing only one species within the genus.**
- **See *Enzo Biochem, Inc. v. Gen-Probe, Inc.*,323 F.3d 956, 966, 63 USPQ2d 1609,1615 (Fed. Cir. 2002); *Noelle v. Lederman,* 355 F.3d 1343, 1350, 69 USPQ2d 1508, 1514 (Fed. Cir. 2004); *Regents of the University of California v.Eli Lilly,* 119 F.3d at 1568, 43 USPQ2d at 1406 (Fed. Cir. 1997) .**

Revised Training Materials-Example 7 (Allelic Variants)

- **Claim 1. An isolated DNA that encodes Protein X having the amino acid sequence SEQ ID: 2. (Genus)**

- **Claim 2. An isolated allele of the DNA according to claim 1, which allele encodes Protein X having the amino acid SEQ ID: 2. (Subgenus)**

Revised Training Materials-Example 7

- **Specification:**
  - **Discloses a DNA, SEQ ID NO: 1 that encodes Protein X (SEQ ID NO: 2) which is a cell surface receptor for adenovirus.**
  - **No allelic sequence information is disclosed.**
  - **Allelic variants of SEQ ID NO: 1 can be obtained by hybridizing SEQ ID NO: 1 to a DNA library made from the same species that yielded SEQ ID NO: 1.**

Revised Training Materials-Example 7

- Claim 1. An isolated DNA that encodes Protein X having the amino acid sequence SEQ ID: 2.
  - Only one species in the claimed genus (SEQ ID NO: 1).
  - However, genetic code provides a known correlation between codon function and structure e.g. cDNA → protein.
  - One skilled in the art would have been able to readily envision all the DNAs capable of encoding SEQ ID NO: 2.
    - Conclusion: Claim 1 genus satisfies WD.

Revised Training Materials-Example 7

- Claim 2. An isolated allele of the DNA according to claim 1, which allele encodes Protein X having the amino acid SEQ ID: 2.
  - "allele": native DNAs that encode protein X.
  - Actual reduction to practice: one species, SEQ ID NO: 1.
  - Structure of one allele does not provide guidance to the existence or structure of other alleles.
  - No information regarding the common attributes that allow one to identify an allele versus any DNA that encodes.
  - Accordingly, one member of this genus is not representative.
  - Conclusion: Claim 2 subgenus fails to satisfy WD.

Revised Training Materials-Example 11

- **Claim 1. An isolated nucleic acid that encodes a polypeptide with at least 85% amino acid sequence identity to SEQ ID NO: 2. (Genus)**

- **Claim 2. An isolated nucleic acid that encodes a polypeptide with at least 85% amino acid sequence identity to a SEQ ID NO: 2; wherein the polypeptide has activity Y. (Subgenus)**

Revised Training Materials-Example 11

Example 11A (Specification):

- **Only nucleic acid SEQ ID NO: 1 encodes the polypeptide of SEQ ID NO: 2 with novel activity Y.**
- **SEQ ID NO: 2 has no significant sequence identity with any known polypeptide or polypeptide family.**

Example 11B: (Specification)- Additionally discloses:

- **Deletion studies identifying 2 domains critical to activity Y.**

- **Proposes: conservative mutations within the domains will retain activity while non-conservative substitutions will not.**
- **Proposes: most mutations outside of the domains will not affect activity Y.**

Revised Training Materials-Example 11

- Claim 1. An isolated nucleic acid that encodes a polypeptide with at least 85% amino acid sequence identity to SEQ ID NO: 2.
  - Actual reduction: single species i.e., SEQ ID NO: 1.
  - "at least 85% identity" is a partial structure e.g. up to 15% of the amino acids may vary from those in SEQ ID NO: 2.
- WD for claim 1: SEQ ID NO: 2 combined with the genetic code would have put one in possession of the genus of nucleic acids that encode SEQ ID NO: 2.

Revised Training Materials-Example 11

- Claim 2. An isolated nucleic acid that encodes a polypeptide with at least 85% amino acid sequence identity to a SEQ ID NO: 2; wherein the polypeptide has activity Y.

  - Encompasses NA's encoding SEQ ID NO: 2 and polypeptides having 85% sequence identity to SEQ ID NO: 2 that have activity Y.
  - SEQ ID NO: 2 and genetic code put one in possession of the genus of nucleic acids that encode SEQ ID NO: 2.
  - No known or disclosed correlation between a structure other than SEQ ID NO: 2 and activity X.
  - Accordingly, SEQ ID NO: 2 is not representative of other proteins having activity X.

- Claim 2 fails to satisfy WD (Ex. 11a result)

Revised Training Materials-Example 11

- **Claim 2. An isolated nucleic acid that encodes a polypeptide with at least 85% amino acid sequence identity to a SEQ ID NO: 2; wherein the polypeptide has activity Y.**

  - **proposes that conservative mutations within the domains will retain activity while non-conservative substitution will not.**
  - **proposes that most mutations outside of the domains will not affect activity Y.**

- **Claim 2 has WD (Ex. 11b result) by establishing structure-function correlation from deletion studies that identify two domains critical to activity Y.**

Revised Training Materials-Example 14

- Description of a mouse antigen provided support for antibodies binding that mouse antigen but, without more, did not support claims to antibodies binding the corresponding human antigen or a generic claim to antibodies binding a corresponding mammalian antigen genus.
- "as long as an applicant has disclosed a 'fully characterized antigen,' either by its structure, formula, chemical name, or physical properties, or by depositing the protein in a public depository, the applicant can then claim an antibody by its binding affinity to that described antigen" . *Noelle v. Lederman*, 355 F.3d 1343, 1349 (Fed. Cir. 2004).

In re Alonso : Use of Antibody Genus: Partially Characterized Antigen

- Based on: *In re Alonso*, 545 F3d 1015, 88 USPQ2d 1849 (Fed. Cir. 2008).

- **Claim. A method of treating neurofibrosarcoma in a human by administering an effective amount of a monoclonal antibody idiotypic to the neurofibrosarcoma of said human, wherein said monoclonal antibody is secreted from a human-human hybridoma derived from the neurofibrosarcoma cells.**

In re Alonso : Disclosure

- Claim. A method of treating neurofibrosarcoma in a human by administering an effective amount of a monoclonal antibody idiotypic to the neurofibrosarcoma of said human, wherein said monoclonal antibody is secreted from a human-human hybridoma derived from the neurofibrosarcoma cells.
- **Specification discloses a method of generating antibodies to tumor cell suspensions and screening them for the ability to cause tumor regression in a patient.**
- **Generated a single monoclonal antibody to a tumor cell suspension prepared from a patient tumor sample that bound a 221KD tumor surface antigen.**
- **Exemplified the regression of a patient's tumor with said monoclonal antibody.**

In re Alonso : Analysis

- Claim. A method of treating neurofibrosarcoma in a human by administering an effective amount of a monoclonal antibody idiotypic to the neurofibrosarcoma of said human, wherein said monoclonal antibody is secreted from a human-human hybridoma derived from the neurofibrosarcoma cells.
- **The claim encompasses a monoclonal antibody genus which is:**

  - Idiotypic to a neurofibrosarcoma of a human patient

  - Therapeutic
- **The prior art teaches that there is considerable antigenic heterogeneity of tumors between patients and metastatic sites within a single patient.**
- **Therefore, the antibodies falling within the claimed genus would be expected to vary substantially.**

In re Alonso : Analysis (Cont.)

- Claim. A method of treating neurofibrosarcoma in a human by administering an effective amount of a monoclonal antibody idiotypic to the neurofibrosarcoma of said human, wherein said monoclonal antibody is secreted from a human-human hybridoma derived from the neurofibrosarcoma cells.
- **A single therapeutic monoclonal antibody was reduced to practice.**
- **The antigen to which the disclosed monoclonal antibody binds was not fully characterized.**
- **Neither the specification nor the prior art provided information regarding which antibody structures predictably would function to treat neurofibrosarcoma.**

In re Alonso : Conclusion (Lack of WD)

- Claim. A method of treating neurofibrosarcoma in a human by administering an effective amount of a monoclonal antibody idiotypic to the neurofibrosarcoma of said human, wherein said monoclonal antibody is secreted from a human-human hybridoma derived from the neurofibrosarcoma cells.
- **A general method of making and identifying antibodies is not enough to describe the procedure for generating and determining whether a given antibody will function in the claimed method.**
- **The single disclosed antibody is insufficiently representative of the variable genus of antibodies encompassed by the claim.**

Summary: WD Antibody Genus/Subgenus Claims

Generic Antibody claim coverage:

- possible when a fully characterized antigen is claimed (*Noelle*).

E.g., An antibody that specifically binds antigen X of SEQ ID. NO.

Summary: WD Antibody Genus/Subgenus Claims (Cont.)

- **Functional Subgenus Antibody claim: may require:**
  - **representative species; and/or**
  - **additional identifying characteristics e.g. "structure, epitope characterization, binding affinity, specificity, or pharmacological properties …." (*Alonso*); and/or**
  - **a structure / function correlation**

using specification and/or state of the prior art.

- **A functional subgenus antibody claim (depending on the limitation) can result in a claim that does not meet WD, as in examples 7 and 11 of the Revised Training Materials.**

Example 1: (high affinity antibody subgenus)

- **Claim 1: An isolated antibody that binds human receptor X which comprises the heavy chain variable region of SEQ ID NO:1 and the light chain variable region of SEQ ID NO:2.**
- **Claim 2: An isolated antibody that exhibits an equilibrium dissociation constant (K_D) of less than 285pM with human receptor X and is comprised of a sequence at least 90% homologous to the heavy chain variable region of SEQ ID NO:1 and a sequence at least 90% homologous to the light chain variable region of SEQ ID NO:2.**
- **NOTE: Claim 2 is an antibody subgenus of claim 1 that includes only those claim 1 antibody compounds that have high affinity receptor X binding.**

Example 1: (Specification)

- Prior art teaches monoclonal and polyclonal antagonist antibodies to cytokine receptor X expressed on human inflammatory cells (e.g. mast cells) were useful in inhibiting inflammation and allergic responses.
- Instant application discloses an isolated high affinity antagonist (HAA) antibody to cytokine receptor X that exhibits an equilibrium dissociation constant (K_D) of less than 285 pM that contains a V_H of SEQ ID NO:1 and a V_L of SEQ ID NO:2.

Ex. 1 (Specification Cont.)

- Specification discloses that conventional phage library/panning techniques based on their HAA antibody can obtain additional antagonist antibodies.
- The instant application encompasses (but does not exemplify) fragments and analogs (deletion/addition/ substitution) that are >90% homologous (sequence identity) to their isolated antibody.

Ex. 1: Claim 1: Analysis/Conclusion

- Claim 1: An isolated antibody that binds human receptor X which comprises the heavy chain variable region of SEQ ID NO:1 and the light chain variable region of SEQ ID NO:2.
- Isolated VL and VH domains retain their antigen-binding activity as the Fv fragment. [1]
- Specification discloses a species within the instant claim scope.
- Prior art establishes a sufficient correlation between antibody (VL and VH) structure and antigen binding.
- Therefore, a claim that defines an antibody that binds receptor X as comprising a VH chain of SEQ ID NO:1 and a VL chain of SEQ ID NO:2 meets WD.

[1] Hayzer et al. Bioconjugate Chemistry 1991 Vol. 2. pp 301-3018.

Ex. 1: Claim 2 (Analysis)

- Claim 2: An isolated antibody that exhibits an equilibrium dissociation constant (K_D) of less than 285pM with human receptor X and is comprised of a sequence at least 90% homologous to the heavy chain variable region of SEQ ID NO:1 and a sequence at least 90% homologous to the light chain variable region of SEQ ID NO:2.
- Claim encompasses antibodies in which up to 10% of the amino acids may vary in both the VH and VL regions of SEQ ID 1 and SEQ ID 2 which would be deemed by one of ordinary skill to be essential to retain high affinity antagonistic binding (K_D of less than 285 pM).
- Discloses only a single species within the instant claim scope.
- There is no teaching identifying what amino acids can be varied within the VL or VH antibody regions and still retain high affinity (Kd< 285pM) antagonistic binding with human receptor X.

Ex.1: Claim 2 (Conclusion: lacks WD)

- Claim 2: An isolated antibody that exhibits an equilibrium dissociation constant (K_D) of less than 285pM with human receptor X and is comprised of a sequence at least 90% homologous to the heavy chain variable region of SEQ ID NO:1 and a sequence at least 90% homologous to the light chain variable region of SEQ ID NO:2.

- **Neither the prior art nor applicant's disclosure defines sufficient representative antibodies and/or sufficient structure/function correlation between modifying the VL or VH regions of their disclosed antibody and the retention of high affinity antagonistic binding to satisfy the WD requirement for claim 2.**

  -result is consistent with Revised Training Materials: example 11 (% identity).

Example 2: (Ab genus: modified CDR's)

- **Claim 3: An isolated antibody that binds to receptor X, said antibody comprises an amino acid sequence that is at least 90% homologous to the 3 heavy chain variable CDRs in SEQ ID NO:1 and an amino acid sequence that is at least 90% homologous to the 3 light chain variable CDRs in SEQ ID NO:2.**

- **CDRs: Complementarity Determining Regions.**

Ex. 2 (Disclosure)

- Claim 3: An isolated antibody that binds to receptor X, said antibody comprises an amino acid sequence that is at least 90% homologous to the 3 heavy chain variable CDRs in SEQ ID NO:1 and an amino acid sequence that is at least 90% homologous to the 3 light chain variable CDRs in SEQ ID NO:2.
- **Discloses prior art antagonist antibodies to cytokine receptor X that are expressed on human inflammatory cells (e.g. mast cells) for use in inhibiting inflammation and allergic responses.**
- **Applicant produces an isolated high affinity antagonist (HAA) antibody to cytokine receptor X with a (K_D) of less than 285 pM that contains a V_H of SEQ ID NO:1 and a V_L of SEQ ID NO:2.**

Ex. 2 (Disclosure cont.)

- Claim 3: An isolated antibody that binds to receptor X, said antibody comprises an amino acid sequence that is at least 90% homologous to the 3 heavy chain variable CDRs in SEQ ID NO:1 and an amino acid sequence that is at least 90% homologous to the 3 light chain variable CDRs in SEQ ID NO:2.
- Applicant identifies by sequence the 3 CDR regions within both the V_H and V_L chains of the HAA antibody.
- Specification discloses conventional phage library/panning techniques which can be used to screen for additional antagonist antibodies.
- Application encompasses (but does not exemplify) fragments and analogs (deletion/addition/ substitution) that are >90% homologous (sequence identity) to their isolated antibody including humanized antibodies.

Ex. 2 (State of the Prior Art)

- Well known that the heavy and light polypeptide chains each contribute three CDRs to the antigen binding region of the antibody molecule.
- The prior art[1] teaches humanization of antibodies by transfer of the 6 CDRs from a donor framework region to an acceptor framework region and retention of antigen binding.

[1]Queen et al., PNAS (1988) 86:10029-10033,

Riechmann et al., Nature (1988) 332:323-327

Ex. 2: (State of the Prior Art: Cont.)

- *Brown et al.* (J Immunol. 1996 May;156(9):3285-91 at 3290 and Tables 1 and 2), describes how a one amino acid change in the VH CDR2 of a particular antibody was tolerated whereas, the antibody lost binding upon introduction of two amino changes in the same region.
- *Vajdos et al.* (J Mol Biol. 2002 Jul 5;320(2):415-28 at 416) teach that amino acid sequence and conformation of each of the heavy and light chain CDRs are critical in maintaining the antigen binding specificity and affinity which is characteristic of the parent immunoglobulin. Aside from the CDRs, the Fv also contains more highly conserved framework segments which connect the CDRs and are mainly involved in supporting the CDR loop conformations, although in some cases, framework residues also contact antigen.

Ex. 2 (Analysis)

- Claim 3: An isolated antibody that binds to receptor X, said antibody comprises an amino acid sequence that is at least 90% homologous to the 3 heavy chain variable CDRs in SEQ ID NO:1 and an amino acid sequence that is at least 90% homologous to the 3 light chain variable CDRs in SEQ ID NO:2.
- **Scope of the claim encompasses antibodies with 6 intact CDRs as well as a subgenus of antibodies that encompass up to 10% variation (fragments and/or analogs) in the 6 CDRs.**
- **Disclose a species within the instant claim scope.**
- **Prior art discloses 6 CDRs as being essential structure of the antibody's binding site, and thus when intact, would provide enough structure to define the antibody's binding site (structure / function correlation) e.g. where amino acid substitutions can be made so as to change (e.g. 6 CDR's) or retain (e.g. constant or variable framework) antigen binding.**

Ex. 2 (Analysis / Conclusion: Lacks WD)

- Claim 3: An isolated antibody that binds to receptor X, said antibody comprises an amino acid sequence that is at least 90% homologous to the 3 heavy chain variable CDRs in SEQ ID NO:1 and an amino acid sequence that is at least 90% homologous to the 3 light chain variable CDRs in SEQ ID NO:2.
- **Prior art for humanization supports obtaining successful antigen binding by transferring the 6 intact CDRs from a donor framework to an acceptor framework.**
- **However, prior art teaches that variation(s) within the CDRs render antigen binding unpredictable.**
- **Therefore, a single antibody species would not be deemed by one of skill in the art to be representative of a claim that defines an antibody that binds antigen X comprising at least 90% homology to the 6 CDR of the VH and VL chains in SEQ ID NO:1 and SEQ ID NO:2.**
- **Accordingly, claim lacks WD.**

Example 3: Single CDR-defined subgenus

- **Claim : An isolated antibody that binds to human antigen X, said antibody comprising a heavy chain variable domain and a light chain variable domain, said heavy chain variable domain comprises the CDR3 in SEQ ID NO:1 (VH).***

*** This Example mirrors an example in the lecture on "Enablement Issues in the Examination of Antibodies", given by Larry R. Helms (SPE, AU 1643) at the June 13, 2007 BCP (http://www.cabic.com/bcp/)**

Ex. 3: Specification

- Claim : An isolated antibody that binds to human antigen X, said antibody comprising a heavy chain variable domain and a light chain variable domain, said heavy chain variable domain comprises the CDR3 in SEQ ID NO:1 (VH).
- Discloses antigen X from human tissue which is over-expressed in cancer tissue vs. normal tissue.
- Applicant produced a series of anti-X antibodies which were not random combinations of VH and VL i.e., they had specific VH domains paired with specific VL domains.
- The VH domains are highly homologous (>75%) to each other and share not only CDR3 but are nearly identical in framework regions i.e. 3-6 amino acids differ out of 124 residues.
- The CDR1 and CDR2 regions of these antibodies share some identity: CDR1 (3/5 identical) and CDR2 (6/16 identical) regions.

Ex. 3: Specification Cont.

- **Claim : An isolated antibody that binds to human antigen X, said antibody comprising a heavy chain variable domain and a light chain variable domain, said heavy chain variable domain comprises the CDR3 in SEQ ID NO:1 (VH).**

- **Analysis of the VL sequences of these antibodies reveals that these domains are highly homologous (>75%) to each other.**

- **The framework regions are nearly identical and the VL domains are identical in CDR1 and CDR2 regions. The CDR3 (8/10 are identical) regions are highly homologous to each other.**

Ex. 3 (State of the Prior Art)

- Prior art methods for screening rely on a two step process where each step results in an antibody.
- However, each step requires one of the variable domains to be a defined sequence and the defined variable domain provides enough structure to obtain an antibody.
- See e.g. Klimka et al., British Journal of Cancer (2000) 83: 252-260; and Beiboer et al., J. Mol. Biol. (2000) 296:833-849.

Ex. 3 (State of the Prior Art: cont.)

- **Prior art methods do not result in an antibody solely by keeping CDR3 in the VH defined and randomizing the rest of the VH and VL domains.**
- **Prior art indicated that, in some instances, the CDR3 region is important. However, this region is not solely responsible for binding. The conformation of other CDRs, as well as framework residues influence binding.**
- **See e.g., MacCallum et al., J. Mol. Biol. (1996) 262: 732-745; Pascalis et al., the Journal of Immunology (2002) 169: 3076-3084; and Casset et al., BBRC (2003) 307, 198-205.**

Ex. 3 (Analysis)

- Claim : An isolated antibody that binds to human antigen X, said antibody comprising a heavy chain variable domain and a light chain variable domain, said heavy chain variable domain comprises the CDR3 in SEQ ID NO:1 (VH).

- **Claim is broadly drawn to any antibody that binds antigen X and comprises a heavy chain variable region comprising CDR3 in SEQ ID NO:1.**

- **Discloses a series of antibodies with highly homologous VH and VL domains and identical VH CDR3 regions.**

Ex. 3 (Analysis cont.)

- Claim : An isolated antibody that binds to human antigen X, said antibody comprising a heavy chain variable domain and a light chain variable domain, said heavy chain variable domain comprises the CDR3 in SEQ ID NO:1 (VH).
- **Neither the specification, nor the prior art provides any examples to support the premise that CDR3 of the VH or VL is solely responsible for antigen binding.**
- **Prior art does not support a definition of an antibody structure solely by defining the CDR3 sequence of a VH or VL.**
- **Therefore, the disclosed species would not be deemed by one of skill in the art to be representative of the claim scope.**

Ex. 3 (Conclusion: Lacks WD)

- **Based on this analysis a claim to an isolated antibody that binds to human antigen X, said antibody comprises a heavy chain variable domain and a light chain variable domain, said heavy chain variable domain comprises the CDR3 in SEQ ID NO:1, does not meet the requirements of 35 U.S.C. 112, first paragraph, for WD.**

Questions

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UNITED STATES PATENT AND TRADEMARK OFFICE

35 U.S.C. 112 2nd paragraph

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This talk follows

A recent DCPEP memo dated 9/2/08 posted

at http://www.uspto.gov/web/patents/memorandum.htm

Entitled:

"Indefiniteness Rejections under 35 USC 112, 2nd Paragraph"

Also note

Another related DCPEP memo dated 9/2/08 posted

at http://www.uspto.gov/web/patents/memorandum.htm

Entitled:

"Rejections under 35 U.S.C. 112, second paragraph, when examining means (or step) plus function claim limitations under 35 U.S.C. 112, sixth paragraph "

Importance of the Claims

"The claims must provide a clear measure of what applicants regard as the invention so that it can be determined whether the claimed invention meets all the criteria for patentability."

MPEP 2173

Claim Interpretation

"[The] manner of claim interpretation that is used by courts in litigation is not the manner of claim interpretation that is applicable during prosecution of a pending application before the PTO."

MPEP 2106, citing *In re Zletz*, 893 F.2d 319, 321-22 (Fed. Cir. 1989).

Importance of Addressing Indefiniteness During Examination

"We [the CAFC] note that the patent drafter is in the best position to resolve the ambiguity in the patent claims, and *it is highly desirable that patent examiners demand that applicants do so in appropriate circumstances* so that the patent can be amended during prosecution rather than attempting to resolve the ambiguity in litigation."

Halliburton Energy Servs. v. M-ILLC 514 F.3d 1244, 1255 (Fed. Cir. 2008) (Emphasis added per 9/2/08 Memo)

Precise, Clear, Correct and Unambiguous

"An essential purpose of patent examination is to fashion claims that are precise, clear, correct, and unambiguous. Only in this way can uncertainties of claim scope be removed, as much as possible, during the administrative process."

MPEP 2106, quoting *In re Zletz*, 893 F.2d 319, 322 (Fed. Cir. 1989).

35 U.S.C. 112, second paragraph

"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."

Primary Purpose of 35 U.S.C. 112, second paragraph

"The primary purpose of the definiteness requirement for claim language is to ensure that the scope of the claims is clear so that the public is informed of the boundaries of what constitutes infringement of the patent."

From 9/2/08 Memo entitled "Indefiniteness Rejections under 35 USC 112, 2nd Paragraph"

When a Claim is Subject to More than One Interpretation

"Where the claim is subject to more than one interpretation and at least one interpretation would render the claim unpatentable over the prior art, examiner should reject the claim as indefinite under 35 U.S.C. 112, second paragraph, and should reject the claim over the prior art based on the interpretation of the claim that renders the prior art applicable."

From 9/2/08 Memo entitled "Indefiniteness Rejections under 35 USC 112, 2nd Paragraph"

Two or More Plausible Constructions

USPTO gives claims the broadest reasonable construction in light of the specification and, if claim is amenable to two or more plausible constructions, applicant is required to amend claim to more precisely define metes and bounds of claimed invention or claim is indefinite under § 112, ¶ 2.

Ex parte Miyazaki, 89 USPQ2d 1207 (BPAI 2008) (expanded panel)

Test for Definiteness at the USPTO

"The test for definiteness under 35 U.S.C. § 112, second paragraph, is whether 'those skilled in the art would understand what is claimed when the claim is read in light of the specification.' "

MPEP 2173.02, quoting *Orthokinetics, Inc. v. Safety Travel Chairs, Inc.,* 806 F.2d 1565, 1576 (Fed. Cir. 1986).

Two Separate Requirements under 35 U.S.C. 112, second paragraph

"…the claims must set forth the subject matter that applicants regard as their invention;

and

the claims must particularly point out and distinctly define the metes and bounds of the subject matter that will be protected by the patent grant."

MPEP 2171

Analyzing Claims for Indefiniteness

"Definiteness of claim language must be analyzed, not in a vacuum, but in light of:

(A) the content of the particular application disclosure;

(B) the teachings of the prior art; and

(C) the claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made."

MPEP 2173.02

Broadest Reasonable Interpretation

"USPTO personnel are to give claims their broadest reasonable interpretation in light of the supporting disclosure."

MPEP 2106, quoting *In re Morris*, 127 F.3d 1048, 1054-55 (Fed. Cir. 1997).

“During patent examination the pending claims must be interpreted as broadly as their terms reasonably allow.

MPEP 2106, quoting *In re Zletz*, 893 F.2d 319, 321 (Fed. Cir. 1989).

Importing Limitations from the Specification

"Limitations appearing in the specification but not recited in the claim should not be read into the claim. . . . Claims must be interpreted 'in view of the specification' without importing limitations from the specification into the claims unnecessarily."

MPEP 2106, citing *E-Pass Techs., Inc. v. 3Com Corp.*, 343 F.3d 1364, 1369 (Fed. Cir. 2003).

Particularly Point Out and Distinctly Claim

"If the claims do not particularly point out and distinctly claim that which applicants regard as their invention, the appropriate action by the examiner is to reject the claims under 35 U.S.C. 112, second paragraph."

MPEP 2171, citing *In re Zletz,* 893 F.2d 319, 13 USPQ2d 1320 (Fed. Cir. 1989)

Rejecting a Claim under 112 2nd Paragraph

"If a rejection is based on 35 U.S.C. 112, second paragraph, the examiner should further explain whether the rejection is based on indefiniteness or on the failure to claim what applicants regard as their invention."

MPEP 2171, citing *Ex parte Ionescu,* 222 USPQ 537, 539 (Bd. App. 1984).

Reasons are Required

"If upon review of a claim in its entirety, the examiner concludes that a rejection under 35 U.S.C. 112, second paragraph, is appropriate, such a rejection should be made and an analysis as to why the phrase(s) used in the claim is 'vague and indefinite' should be included in the Office action."

MPEP 2173.02

Consideration of Applicant's Arguments

"If applicants traverse the rejection, with or without the submission of an amendment, and the examiner considers applicant's arguments to be persuasive,

the examiner should indicate in the next Office communication that the previous rejection under 35 U.S.C. 112, second paragraph, has been withdrawn and provide an explanation as to what prompted the change in the examiner's position."

MPEP 2173.02

No *Per Se* Rules

"Office policy is not to employ *per se* rules to make technical rejections.

Examples of claim language which have been held to be indefinite set forth in MPEP § 2173.05(d) are fact specific and should not be applied as *per se* rules."

MPEP 2173.02

Particular 35 U.S.C. 112 2nd Situations

Lack of Antecedent Basis	Example 1
“Use” Claims	Example 2
Preamble and Wherein clauses	Example 3
Exemplary Embodiments	Example 4
Derivatives and Derived From	Examples 5A, 5B, 5C and 6
Chemical Formula does not Define all variable	Example 7A
Variable for Chemical Formula Defined in Specification	Example 7B
Chemical Formula Includes Functional Limitation	Example 8
Reference to Another Claim	Example 9
Reference to A Cancelled Claim	Example 10
Reference to A Withdrawn Claim	Example 11
Dependent Claim does not Further Limit Independent Claim	Example 12
Punctuation and Typographical Errors	Examples 13, 14
Use of Trademarks	Example 15

See MPEP 2171 for other particular situations.

Example 1: Lack of Antecedent Basis

Claim 1. An apparatus comprising a "translator controller" … wherein "the linear translator"…

"The claim is ambiguous and a rejection under 35 U.S.C 112, second paragraph based upon a lack of proper antecedent basis is appropriate. In this case, it is unclear if the "linear translator" is a new element or is the previously introduced "translator controller.""

"[I]t is unclear whether the linear translator and the translator controller are the same element or different elements, and if different, how they relate to each other."

A rejection for indefiniteness using FP 7.34.01 and 7.34.05 is warranted.

The quoted text is from Example 2 of the 9/2/08 Memo

Product and/or Process Claims?

"A single claim which claims both an apparatus and the method steps of using the apparatus is indefinite under 35 U.S.C. 112, second paragraph."

MPEP 2173.05(p), citing *IPXL Holdings v. Amazon.com, Inc.,* 430 F.2d 1377, 1384, 77 USPQ2d 1140, 1145 (Fed. Cir. 2005); *Ex parte Lyell,* 17 USPQ2d 1548 (Bd. Pat. App. & Inter. 1990).

“Use” Claims

“Attempts to claim a process without setting forth any steps involved in the process generally raises an issue of indefiniteness under 35 U.S.C. 112, second paragraph.”

MPEP 2173.05(q)

Example 2: “Use” Claims

Claim 2. The use of a monoclonal antibody of claim 1 to isolate and purify human fibroblast interferon.

This claim “was held to be indefinite because it merely recites a use without any active, positive steps delimiting how this use is actually practiced. *Ex parte Erlich*, 3 USPQ2d 1011 (Bd. Pat. App. & Inter. 1986)”

“[R]eject a “use” claim under alternative grounds based on 35 U.S.C. 101 and under 35 U.S.C. 112”, using FPs 7.05, 7.05.01, 7.34.01 and 7.34.12 (essential steps missing).

Quoted text from MPEP 2173.05(q)

Example 3: Effect of Preamble in Process Claim

Claim 1. A method of treating diabetes comprising administering compound X to a subject in need thereof.

This claim is considered complete with respect to 35 USC 112 2nd paragraph. There is no requirement that a preamble need to be repeated in a final "wherein" clause.

Example 4: Exemplary Embodiments

Claim 1. A composition comprising Product X and a protease, for example, chymotrypsin.

Because protease (generic term) and chymotrypsin (a specific type of protease) are not identical in scope, the use of the phrase “for example” raises the question as to which term is required by the claim. A rejection under 35 U.S.C 112 2nd is warranted using FP 7.34.01 and 7.34.08 along with the following explanation.

Regarding claim 1, “the phrase “for example” renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention.”

Example 5A: Derivative

Claim 1. A vaccine comprising a protein having SEQ ID NO: 1 or a derivative thereof and further comprising a pharmaceutically acceptable adjuvant.

Assume for this example that derivatives of SEQ ID NO: 1 are not clearly defined in specification or in the prior art.

Make a 2nd paragraph rejection using FP 7.34.01 along with any other appropriate rejections or objections.

Example 5B: Derivative

Claim 1. A vaccine comprising a protein having SEQ ID NO: 1 or a derivative thereof and a pharmaceutically acceptable adjuvant.

Assume for this example that derivatives of SEQ ID NO: 1 are not clearly defined in specification. However, SEQ ID NO: 1 and some variants thereof are well know in the prior art.

Make a 112 2nd paragraph rejection using FP 7.34.01 along with any other appropriate rejections or objections.

Example 5C: Derivative

Claim 1. A vaccine comprising a protein having SEQ ID NO: 1 and a pharmaceutically acceptable adjuvant comprising BSA or a derivative of BSA.

Assume for this example that derivatives of BSA were well known in the prior art and/or are clearly defined in specification.

Do not make a rejection under 35 USC 112, 2nd paragraph over derivative.

Example 6: "Derived From"

Claim 1. A composition comprising neural stem cells derived from a spinal cord.

The specification teaches that neural stem cells may be isolated from, i.e., derived from a spinal cord. Although this claim is broad, no issues are raised under 35 U.S.C. 112, 2nd paragraph with regard to the term "derived from" in this situation.

Breadth

"Breadth of a claim is not to be equated with indefiniteness."

MPEP 2173.04, citing *In re Miller,* 441 F.2d 689,169 USPQ 597 (CCPA 1971).

"Undue breadth of the claim may be addressed under different statutory provisions, depending on the reasons for concluding that the claim is too broad."

MPEP 2173.04

Claims to Chemical Formula

"A claim to a chemical compound is not indefinite merely because a structure is not presented or because a partial structure is presented."

MPEP 2173.05(t), citing *In re Fisher,* 427 F.2d 833, 166 USPQ 18 (CCPA 1970)

"Chemical compounds may be claimed by a name that adequately describes the material to one skilled in the art."

MPEP 2173.05(t), citing *Martin v. Johnson,* 454 F.2d 746, 172 USPQ 391 (CCPA 1972)

Claims to Chemical Formula (cont.)

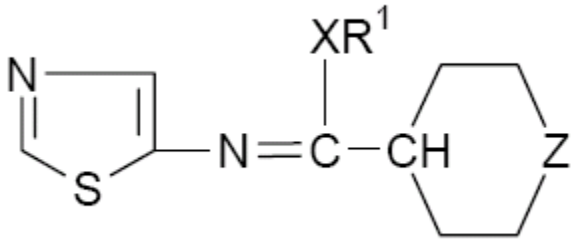
"A compound of unknown structure may be claimed by a combination of physical and chemical characteristics. . . .

A compound may also be claimed in terms of the process by which it is made without raising an issue of indefiniteness."

MPEP 2173.05(t), citing *Ex parte Brian,* 118 USPQ 242 (Bd. App. 1958).

Example 7A: Chemical Formula Does not Define All Variables

Claim 1. A compound having Formu



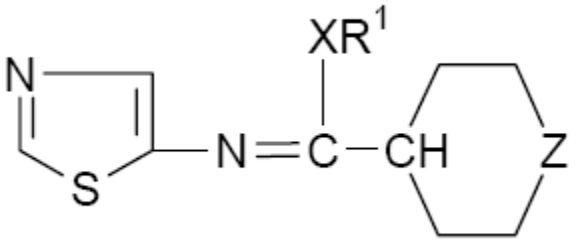
wherein R1 is methyl or phenyl and X is selected from oxygen and sulfur.

In this example, assume that the specification did not provide any definition for “Z”. Neither does the claim provide a definition for the variable “Z”.

Reject Claim 1 under 35 U.S.C 112 2nd paragraph using FP 7.34.01.

Example 7B: Variable Recited in Chemical Formula is Defined in Specification

Claim 1. A compound having Formula 1



wherein R1 is methyl or phenyl and X is selected from oxygen and sulfur.

Claim 1 does not define variable “Z”. In this example, assume that the specification provides that “Z” is any appropriate linker for the two methylene moieties adjacent to Z.

In this example, no rejection under 35 U.S.C 112 2nd paragraph would be warranted.

Functional Terms

"A functional limitation is an attempt to define something by what it does, rather than by what it is (e.g., as evidenced by its specific structure or specific ingredients). There is nothing inherently wrong with defining some part of an invention in functional terms. Functional language does not, in and of itself, render a claim improper."

MPEP 2173.05(g), citing *In re Swinehart,* 439 F.2d 210, 169 USPQ 226 (CCPA 1971).

Functional Terms (cont.)

"When a claim limitation is defined in purely functional terms, the task of determining whether that limitation is sufficiently definite is a difficult one that is highly dependent on context (e.g., the disclosure in the specification and the knowledge of a person of ordinary skill in the relevant art area)."

Halliburton Energy Servs. v. M-ILLC, 514 F.3d 1244, 1255 (Fed. Cir. 2008)

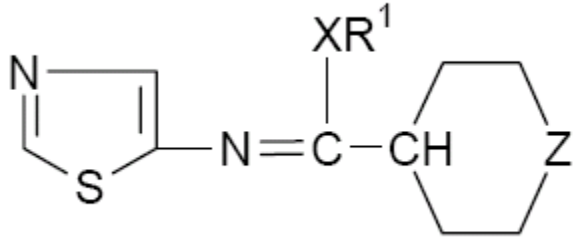
Functional Terms for Chemical Compounds

"It was held that the limitation used to define a radical on a chemical compound as 'incapable of forming a dye with said oxidizing developing agent' although functional, was perfectly acceptable because it set definite boundaries on the patent protection sought."

MPEP 2173.05(g), citing *In re Barr,* 444 F.2d 588, 170 USPQ 33 (CCPA 1971).

Example 8: Chemical Formula Which Includes a Functional Limitation

Claim 1. A compound having Formula 1



wherein X is oxygen, Z is sulfur and R1 is a leaving group.

The claim provides a functional limitation for the variable “R1”. The specification defines “leaving group” in a manner consistent with what is known in the art.

Although the claim is broad with respect to R1, no rejection under 35 U.S.C 112 2nd paragraph is warranted.

Numerical Ranges and Amounts

"Use of a narrow numerical range that falls within a broader range in the same claim may render the claim indefinite when the boundaries of the claim are not discernible.

Description of examples and preferences is properly set forth in the specification rather than in a single claim."

MPEP 2173.05(c)

Numerical Ranges and Amounts (cont.)

"A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c)."

FP 7.34.04

1st and 2nd Paragraphs of 35 U.S.C. 112 are Separate and Distinct

"If a description or the enabling disclosure of a specification is not commensurate in scope with the subject matter encompassed by a claim, that fact alone does not render the claim imprecise or indefinite or otherwise not in compliance with 35 U.S.C. 112, second paragraph."

MPEP 2174

Relationship Between 112 2nd and Art Rejections

"When making a rejection over prior art in these circumstances, it is important for the examiner to point out how the claim is being interpreted."

MPEP 2173.06

Relationship Between 112 2nd and Art Rejections (cont.)

"[W]here the degree of uncertainty is not great, and where the claim is subject to more than one interpretation and at least one interpretation would render the claim unpatentable over the prior art, an appropriate course of action would be for the examiner to enter two rejections:

(A) a rejection based on indefiniteness under 35 U.S.C. 112, second paragraph; and

(B) a rejection over the prior art based on the interpretation of the claims which renders the prior art applicable."

MPEP 2173.06, citing *Ex parte Ionescu,* 222 USPQ 537 (Bd.App. 1984).

Relationship Between 112 2nd and Art Rejections (cont.)

"Where there is a great deal of confusion and uncertainty as to the proper interpretation of the limitations of a claim, it would not be proper to reject such a claim on the basis of prior art. . . . [A] rejection under 35 U.S.C. 103 should not be based on considerable speculation about the meaning of terms employed in a claim or assumptions that must be made as to the scope of the claims."

MPEP 2173.06, citing *In re Steele,* 305 F.2d 859, 134 USPQ 292 (CCPA 1962).

Clarity and Precision

"Examiners are encouraged to suggest claim language to applicants to improve the clarity or precision of the language used, but should not reject claims or insist on their own preferences if other modes of expression selected by applicants satisfy the statutory requirement."

MPEP 2173.02

Amendments Must Not Introduce New Matter

35 U.S.C. 132(a) provides that “[n]o amendment shall introduce new matter into the disclosure of the invention.”

Examiner's Suggestions

"If the language used by applicant satisfies the statutory requirements of 35 U.S.C. 112, second paragraph, but the examiner merely wants the applicant to improve the clarity or precision of the language used, the claim must not be rejected under 35 U.S.C. 112, second paragraph, rather, the examiner should suggest improved language to the applicant."

MPEP 2173.02

Claim Objections

"If the form of the claim (as distinguished from its substance) is improper, an "objection" is made.

The practical difference between a rejection and an objection is that a rejection, involving the merits of the claim, is subject to review by the Board of Patent Appeals and Interferences, while an objection, if persisted, may be reviewed only by way of petition to the Director of the USPTO."

MPEP 706.01

Product by Process Claims

"A product-by-process claim, which is a product claim that defines the claimed product in terms of the process by which it is made, is proper."

MPEP 2173.05(p)

Reference to Limitations in Another Claim

"A claim which makes reference to a preceding claim to define a limitation is an acceptable claim construction which should not necessarily be rejected as improper or confusing under 35 U.S.C. 112, second paragraph."

MPEP 2173.05(f)

Example 9: Reference to Another Claim

"For example, claims which read:

"The product produced by the method of claim 1."

or

"A method of producing ethanol comprising contacting amylose with the culture* of claim 1 under the following conditions....."

are not indefinite under 35 U.S.C. 112, second paragraph, merely because of the reference to another claim."

*assuming there is only one culture in claim 1.

MPEP 2173.05(f)

Example 10: Reference to a Canceled Claim

Claim 1. Cancelled.

Claim 2. The product produced by the method of claim 1.

Claim 2 should rejected under 35 USC 112 2nd using FP 7.34.01 and then examined under remaining statutes.

Example 11: Reference to a Withdrawn Claim

Claim 1. (Withdrawn) A method of ….

Claim 2. The product produced by the method of claim 1.

Claim 2 should be objected to for depending upon a withdrawn claim using FP 7.29.01, as follows:

Claim 2 is objected to because of the following informalities: for depending upon a withdrawn claim . Appropriate correction is required.

Example 12: Dependent Claim Fails to Further Limit Independent Claim

Claim 1. A DNA molecule comprising SEQ ID No 1.

Claim 2. The DNA of Claim 1 which consists of 100 or fewer nucleotides of SEQ ID No 1.

Assume for this example that SEQ ID NO 1 is 200 nucleotides in length.

Claim 2 should be objected to for not further limiting claim 1 using FP 7.36, as follows:

Claim 2 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The DNA molecule of claim 2 reads upon fragments of the DNA molecule of Claim 1. Because claim 2 does not require the entire SEQ ID No 1, Claim 2 is broader in scope than its independent claim 1.

MPEP 608.01(n)

Example 13: Permitted Parentheses

Claim 1. A composition comprising Product X and a glycerol (glycerin).

Because glycerol equals glycerin, the use of parentheses is permitted.

"If one skilled in the art is able to ascertain in the example above, the meaning of the terms … in light of the specification, 35 U.S.C. 112, second paragraph, is satisfied." No rejection is warranted under 35 USC 112. 2nd paragraph.

MPEP 2173.02

Example 14: Problematic Parentheses

Claim 1. A composition comprising Product X and a protease (chymotrypsin).

Because protease (generic term) and chymotrypsin (a specific type of protease) are not identical in scope, the use of parentheses raises the question as to which term is required by the claim.

A rejection under 35 U.S.C 112 2nd is warranted using FP 7.34.01 and FP 7.34.04 (claim uses both narrow and broad limitations).

Example 15: Use of Trademarks

Claim 1. A patch comprising Product A and a Velcro attachment.

VELCRO® is a Registered Trademark denoting a synthetic notion.

Use FP 7.34.01 and 7.35.01 to reject Claim 1. Use FP 6.20 to object to the use of the trademark.

"Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See Ex parte Simpson, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name."

MPEP 608.01(v) and 2173.05(u)

UNITED STATES PATENT AND TRADEMARK OFFICE

Questions?

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UNITED STATES
PATENT AND
TRADEMARK OFFICE

Inherency

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Inherency

- **The rule that anticipation can be inferred despite a missing element in a prior-art reference if the missing element is either necessarily present in or a natural result of the product or process and a person of ordinary skill in the art would know it (Black's Law Dictionary, 8th Ed. 2004)**

- **Can also be asserted by applicant when amending the specification and/or the claims or when asserting priority to demonstrate support and avoid new matter**

Inherency

- **Structure**
- **Use**
- **Advantage or Property**

Inherency

- **Inherent feature need not have been recognized in the prior art**

Atlas Powder v. IRECO, 190 F.3d 1342, 51 USPQ2d 1943 (Fed. Cir. 1999)

Inherency

- **Inherency cannot be established by probabilities or possibilities**
- **The mere fact that a certain thing may result from a given set of circumstances is not sufficient**

In re Oelrich, 666 F.2d 578, 212 USPQ 323 (CCPA 1981)

In re Runion, 989 F.2d 1201 (Fed. Cir. 1993) (Nonprecedential)

- **Claim:**
  - **A bird feeder with pan for holding the food with one vertical surface having an abrasive means for abrading beaks of birds as they feed**
- **Prior art:**
  - **A baking pan for baking bread within which vegetable grit was coated on all of the surfaces to ensure easy removal of the bread by tilting or overturning the pan**

In re Runion, 989 F.2d 1201 (Fed. Cir. 1993) (Nonprecedential)

- Board found that the grit coating of the bread pan performed the function of the claim, i.e. abrading bird beaks
- Court disagreed, determining that a surface described as “rough” or “pebbled” need not necessarily be “abrasive”
- The explanation of the character of the bread pan coating was not consistent with the explanation of the abrasive means in the specification

Inherency

- **Structure**
- **Use**
- **Advantage or Property**

Chen v. Bouchard, 347 F.3d 1299, 68 USPQ2d 1705 (Fed. Cir. 2003)

- In parent application, Chen claims 7-substituted fluorotaxols and discloses a process to produce mixture of fluorotaxols
- Application is allowed but Chen petitions to withdraw from issue due to error and then files a CIP with new claims and new drawings to 7,8-cyclopropataxol

Chen v. Bouchard, 347 F.3d 1299, 68 USPQ2d 1705 (Fed. Cir. 2003)

- Interference is instituted between Chen and Bouchard over claims to the 7,8-cyclopropataxols in the CIP
- Chen attempted to rely on filing date of parent application to establish earlier conception and reduction to practice
- Board denied benefit claim and found Chen to be the junior party, due to lack of adequate written description of the count in the parent

Chen v. Bouchard, 347 F.3d 1299, 68 USPQ2d 1705 (Fed. Cir. 2003)

- Chen appealed and argued inherency to support claim for benefit
- Chen asserted that since disclosed methods invariably produced the cyclopropataxols, the products inherently had the structures in the counts
- Chen argued that it should not matter what the inventors initially believed was the result of the disclosed method or when the error was discovered

Chen v. Bouchard, 347 F.3d 1299, 68 USPQ2d 1705 (Fed. Cir. 2003)

- Bouchard argued that Chen never described any compounds of the counts
- Bouchard pointed to the NMR and mass spec data in the parent application which corresponded only to the erroneously-identified compounds

Chen v. Bouchard, 347 F.3d 1299, 68 USPQ2d 1705 (Fed. Cir. 2003)

- Court agreed with Bouchard
- Court affirmed the Board's holding that the subject matter of the count was not adequately described in Chen's earlier application
- Court distinguished cases relied upon by Chen

Chen v. Bouchard, 347 F.3d 1299, 68 USPQ2d 1705 (Fed. Cir. 2003)

- Cases relied upon by Chen
  - In re Nathan, 328 F.2d 1005, 140 USPQ 601 (CCPA 1964)
  - In re Magerlein, 346 F.2d 609, 145 USPQ 683 (CCPA 1965)
  - Spero v. Ringold, 377 F.2d 652, 153 USPQ 726 (CCPA 1967)
  - Regents of the University of New Mexico v. Knight, 321 F.3d 1111, 66 USPQ2d 1001 (Fed. Cir. 2003)

Schering Corp. v. Geneva Pharmaceuticals, 339 F.3d 1373, 67 USPQ2d 1664 (Fed. Cir. 2003)

- Claim recited descarboethoxyloratidine (DCL)
- DCL is a metabolite formed in the body after administration of loratidine
- DCL is also an antihistimine that does not make the user sleepy
- Infringement proceeding between patent holder and generic manufacturers
- Invalidity based on anticipatory prior art was alleged and summary judgment was granted in favor of generic manufacturers by the district court

Schering Corp. v. Geneva Pharmaceuticals, 339 F.3d 1373, 67 USPQ2d 1664 (Fed. Cir. 2003)

- Claim to compound was construed by the district court to cover compound in all forms, wherever found
- Prior patent disclosed administration of loratidine to patients
- Prior patent did not explicitly disclose DCL and did not expressly refer to metabolites of loratidine

Schering Corp. v. Geneva Pharmaceuticals, 339 F.3d 1373, 67 USPQ2d 1664 (Fed. Cir. 2003)

- Evidence showed that DCL is an inevitable consequence of loratidine administration
- Court held that prior art administration of loratidine to patients inherently anticipated claims to the DCL compound
- Court points out that patent protection is available to metabolites of known drugs but cautions proper claiming

Inherency

- Structure
- **Use**
- Advantage or Property

Ex parte Novitski, 26 USPQ2d 1389 (BPAI 1993)

- Claim for protecting a plant from pathogenic nematodes comprised step of inoculating the plant with nematode-inhibiting strain of *Pseudomonas cepacia*
- Prior art disclosed inoculating plants with *P. cepacia* type Wisconsin 526 to inhibit fungal pathogens
- *P. cepacia* type Wisconsin 526 inhibited nematodes

Mehl/Biophile International Corp. v Milgraum, 192 F.3d 1362, 52 USPQ2d 1303 (Fed. Cir. 1999)

- Claim recited laser hair removal requiring vertical alignment of the laser light applicator over a hair follicle and applying a pulse of laser energy of a wavelength that is readily absorbed by the melanin of the papilla and has a dose of sufficient energy for sufficient duration to damage the papilla such that hair regrowth is prevented and scarring of the surrounding skin is avoided
- Prior art relied upon for anticipation was a manual for laser use for tattoo removal and a research paper discussing effects of laser energy on melanosomes in guinea pig skin

Mehl/Biophile International Corp. v Milgraum, 192 F.3d 1362, 52 USPQ2d 1303 (Fed. Cir. 1999)

- Court found vertical alignment was not inherent in the laser manual – the manual did not discuss hair follicles and only teaches "aiming" the laser at skin pigmented by a tattoo and the court found no necessary relationship between the location of the tattoo and the hair follicle opening
- Court found vertical alignment was inherent in research article because the article specifically mentioned disruption of hair follicles and stated that the laser was held in contact with the animals' skin

Perricone v. Medicis Pharmaceutical Corp., 432 F.3d 1368, 77 USPQ2d 1321 (Fed. Cir. 2005)

- Infringement proceeding where defendant alleged invalidity based on anticipation by inherency
- Claims recited methods of treating sunburned skin
- Prior patent disclosed the same composition as suitable for general topical application to the skin or hair
- District court found that the prior composition would have inherently functioned in the treatment of sunburned skin when topically applied to the skin

Perricone v. Medicis Pharmaceutical Corp., 432 F.3d 1368, 77 USPQ2d 1321 (Fed. Cir. 2005)

- Federal Circuit disagreed, concluding that sunburned skin is not analogous to all skin surfaces
- Since claim required treatment of sunburned skin, the issue was not whether the prior art's composition would have inherently treat sunburned skin if applied (it would), but whether the prior art disclosed the application of the composition to sunburned skin (it did not)

Inherency

- Structure
- Use
- **Advantage or Property**

In re Cruciferous Sprout Litigation, 301 F.3d 1343, 64 USPQ2d 1202 (Fed. Cir. 2002)

- Claim recited method of preparing a food product rich in glucosinolates and rich in high Phase 2 enzyme-inducing potential comprising germinating cruciferous seeds and harvesting sprouts to form a food product
- Prior art taught germinating broccoli seeds, harvesting the sprouts and selling them as a food product
- District court found inherent anticipation of the claim

In re Cruciferous Sprout Litigation, 301 F.3d 1343, 64 USPQ2d 1202 (Fed. Cir. 2002)

- Plaintiff contended that the district court failed to treat the preamble ("rich in glucosinolates" and "high Phase 2 enzyme-inducing potential") as a limitation
- Plaintiff also contended that the second phrase should be limited to require "at least 200,00 units per gram fresh weight of Phase 2 enzyme-inducing potential" to meet the limitation of "high" enzyme-inducing potential

In re Cruciferous Sprout Litigation, 301 F.3d 1343, 64 USPQ2d 1202 (Fed. Cir. 2002

- Federal Circuit found that the phrases were limitations of the claim
- However, the court also held that Plaintiff's proposed claim construction of those terms was improperly limiting in view of the record
- As a result, the court found that the broccoli sprouts of the prior art inherently had the claimed property and therefore inherently anticipated the claims

Highlights and Guidance

- **The Examiner must provide rationale or evidence to support a conclusion of inherency**
- **Once the Examiner presents a *prima facie* case to support a conclusion of inherency, the burden shifts to the Applicant to show that there is no inherency**

Highlights and Guidance

- Structural inherency is more easily asserted if corroborating evidence is present in the specification
- Claims to compounds may not be patentable if the compounds existed in the prior art regardless of whether they were identified or recognized, but methods of use and pharmaceutical compositions for that use may be more successful

Highlights and Guidance

- **Claims to products, compositions or articles of manufacture that are claimed functionally may not be patentable if the evidence indicates that a prior art product, composition or article of manufacture that meets all structural limitations is suitable for or capable of performing the claimed function**

Highlights and Guidance

- **Recognition of a new use or inherent property of a prior art compound, product, composition or article of manufacture may not be patentable in claims directed to compound, product, composition or article of manufacture, but may be more successful in method claims**

MPEP Citations

- 2112 – Requirements of rejections based on inherency
  - 2112.01 – Composition, product and apparatus claims
  - 2112.02 – Process claims
- 2131.01 – Multiple references may be used in a 102 rejection to support the primary reference to show inherency – supportive reference(s) may be post-filing

Thank You!

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