Sequence Rule Compliance, PatentIn and Appeal Issues
Sequence Rule Compliance
Sequence Rule Compliance

- Original US sequence rules, effective October 1, 1990, published in Federal Register
  - Vol. 55, no. 84, May 1, 1990, p. 18230

- Revised US sequence rules, effective July 1, 1998, published in Federal Register
  - Vol. 63, No. 104, June 1, 1998, p. 29620
Why do we have the Sequence Rules?

Publication issues
- Standard format for publication in sequence databases makes automation possible

Search issues
- Standard format makes automated sequence searches possible
Sequence Rule Compliance

Which cases must comply?

- If a nucleic acid or protein sequence is disclosed in the patent application for any reason it MUST comply with the format requirements of the sequence rules.
  
  - The reason for the disclosure is not a factor in determining compliance.
Sequence Rule Compliance

- Length requirements
  - Nucleic acid sequence
    - at least 10 nucleotides
    - at least 4 of which are specifically defined
  - Protein sequence
    - at least 4 amino acids
    - at least 4 of which are specifically defined
Sequence Rule Compliance

- “Specifically defined” means not “n” or “Xaa”
- Examples of specifically defined nucleotides
  - a, c, t, g, u, r (=g or a), s (=g or c)
- Examples of specifically defined amino acids
  - Ala, Ser, Thr, Glu
Sequence Rule Compliance

 Exceptions

- Protein sequences including a required D amino acid are **exempt** from compliance
  - If an Xaa may be a D amino acid as one of the choices then the sequence is **not exempt**
Filing your sequence listing electronically is as easy as it gets.

Attach the sequence listing as a text file and the PTO’s automated systems will do the rest.
Sequence Rule Compliance - Electronic Filing System

- SCORE gets Sequence Listing
- Processes it through verification software
- Enters it into ABSS if in compliance
- Sends message to send Notice to Comply if not in compliance
Sequence Rule Compliance - Helpful Hints

- Which file to submit as the CRF
  - DO submit the file called, “filename.txt” as the CRF
  - DO NOT submit files with extensions of prj, doc, pdf as the CRF
Sequence Rule Compliance - Helpful Hints

- Requesting transfer of CRF from parent is problematic when filing a continuation application via EFS
  - Transfer request includes asking to transfer the CRF but a new paper copy is required
  - In EFS include request but also a pdf copy of the sequence listing as the “paper” copy
Transfer of CRF (continued)

- Problem comes when “paper” copy of sequence listing is filed as txt file
- SCORE creates another sequence listing so there are two in the case
- Which one is the official copy?
Jumbo Sequence Listings

— Use CD rules for these

• Three copies labeled Copy 1, Copy 2 and CRF
• If your sequence listing is big, PatentIn will prompt you to insert a CD
Variable length sequences

- e.g., Val Leu (Xaa)\textsubscript{3-5} Ser Cys
- A recognized problem
- Write as on next slide
Sequence Rule Compliance - Helpful Hints

- <210>  1
- <211>  9
- <212>  PRT
- <213>  Abies alba

- <220>
- <221>  misc_feature
- <222>  (3)..<(7)
- <223>  Xaa may be any naturally-occurring amino acid and any two may be absent

- <400>  1
- Val Leu Xaa Xaa Xaa Xaa Xaa Xaa Ser Cys
-  1     5
Rule 183 petition to waive the sequence rules because the sequence listing is very large will not be granted.

— This is one of the main reasons we have the sequence rules
Sequence Rule Compliance

Where to Get Help

- Help with Notice to Comply:
  - Mark Spencer at (571) 272-2533

- General Compliance Questions:
  - Bob Wax at (571) 272-0623
  - Dave Nguyen at (571) 272-0731
PatentIn
PatentIn

- Designed to expedite the preparation of patent applications containing nucleic acid and amino acid sequences

- PatentIn 3.5 generates sequence listings that comply with all format requirements specified in WIPO Standard ST.25
US Rule refers extensively to World Intellectual Property Organization Standard ST.25 – the two rules were developed together

First Point of Contact

Patent Electronic Business Center

Phone toll-free at 866-217-9197

Or Email to

EBC@uspto.gov
Second Point of Contact

Bob Wax

(571) 272-0623

patin3help@uspto.gov

Response is typically within one business day except for weekends and holidays
Can now import a PatentIn-generated ST.25 sequence listing file

Creates a new PatentIn project

Trust but verify since the data may not be 100% compliant with ST.25

For example, feature data for supplemental amino acid sequences may be missing
Organism is mandatory

- Name the organism if it is known
- Scientific name (*Genus species*)
- Or use Artificial Sequence and define in Features
  - Artificial *anything* now acceptable but not preferred
- Or use Unknown and define in Features
Artificial Sequence

- Feature description should answer the question, “Why did you choose Artificial Sequence as the organism?”
Artificial Sequence

- Information relating to the source of the material is needed
  - Isolated from the natural source
  - Synthesized
Artificial Sequence

- Acceptable explanations
  - “oligonucleotide”
  - “synthetic construct”
A primer’s sequence usually matches the sequence of the DNA to be amplified, so pick that organism rather than Artificial Sequence.
Unknown

- Information relating to why the organism is unknown is needed
  - Source organism never identified
  - From a mixture of organisms

- Do not use Unknown Organism
The sequence rules require that if a nucleic acid sequence contains an "n" or an amino acid sequence contains an "Xaa", a definition in fields <220> through <223> must be provided.
Xaa and n must be defined in the Features section
  – Use misc_feature to define
  – Each position must be identified
PatentIn 3.5 will provide the definitions for you

- Standard definition for nucleotides is, “n is a, c, g or t”
- Standard definition for proteins is, “Xaa may be any naturally-occurring amino acid”
PatentIn – Screen Shots
PatentIn – Screen Shots
PatentIn – Screen Shots

Note: Items marked with * are required fields.

* Title Of Invention: 

Current Application Number: 
(US 07/999,999 or PCT/US 96/999999)

Current Filing Date: 
(YYYY-MM-DD)

* Application File Reference: 

Validate  Save Project  OK  Cancel  Help
PatentIn – Screen Shots
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PatentIn – Screen Shots
PatentIn – Screen Shots
PatentIn

Sequence Compliance Statistics


- PatentIn Used
- Compliant PatentIn
- FastSeq Used
- Compliant FastSeq
- Other Software
- Compliant Other

Percent Program Used/Percent In Compliance

- 2000: 52% PatentIn Used, 39% Compliant PatentIn, 29% FastSeq Used, 26% Compliant FastSeq, 12% Other Software, 16% Compliant Other
- 2004: 68% PatentIn Used, 60% Compliant PatentIn, 21% FastSeq Used, 18% Compliant FastSeq, 8% Other Software, 6% Compliant Other
- 2008: 76% PatentIn Used, 63% Compliant PatentIn, 16% FastSeq Used, 14% Compliant FastSeq, 6% Other Software, 4% Compliant Other
Appeal Issues
Appeal Issues

- Preappeal conferences
    - Extended in OG notice dated February 7, 2006
    - Provides avenue of review before writing Appeal Brief
    - Fresh look at the issues raised
1600 Pre-Appeal Conferences as of Midyear FY 08

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Observations on Preappeal Conferences

- Honest effort to have a fresh look at prosecution history and provide careful reconsideration
- Attorneys do not always adhere to precept of arguing examiner error, often a rehash of previous arguments
- Another chance to look for allowable subject matter and prevent an appeal
## Corps Wide Pre-Appeal Conferences as of midyear FY 08

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Appeal Issues

- Appeal conferences
  - An appeal conference is mandatory in all cases in which an acceptable brief has been filed (MPEP 1207.01)
    - Attended by examiner, mentor if any, SPE and second SPE or Appeals Specialist TQAS
    - Final assessment of appropriateness of rejections in view of Appellant’s arguments, strategy session for writing Examiner’s Answer
### 1600 Appeal Conferences as of midyear FY 08

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## Corps Wide Board of Appeals Statistics as of midyear FY 08

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Appeal Issues

Observations on Appeal conferences

- Issues usually pretty well set
- Final opportunity to find allowable subject matter
- Helps examiner focus on issues and best way to write answers to arguments
Bob Wax
robert.wax@uspto.gov
(571) 272-0623
Adiós, До Свидания, Arrivederci, Auf Wiedersehen, Au Revoir, Later Dude, Ta, Ciao, Aloha, Sayonara, שלום, Last One Out Turn out the Lights