US patent practice - recent trends in international harmonization

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US patent practice – perspective from foreign inventors

- United States an important internal market
  - especially for IT and Biotech
- Holding a US patent can exclude competitors, even in countries where invention not patented
- US patent law seen as complex and confusing

Today's topic - Disappearing differences

- Major differences between US practice and other countries
- Patent reform legislation in the US
- Recent decisions/trends in US biotech practice
  - Utility guidelines
  - In re Fisher – patentability of EST's in the US

Some major differences in US practice

- First to file vs. first to invent
- Grace period
- Who can file application
- Best mode requirement
- What counts as prior art
- Limited opposition after grant
- Patentable subject matter
  - No morality clause
  - No list of excluded subject matter, e.g., in EPO methods of treatment, animal and plant varieties etc not patentable
  - Traditionally more liberal standard of review for software, biotech, business methods

Patent harmonization

- Differences slowly eroding
- Past examples of harmonization
  - 20 year patent term
  - Inventions made abroad can be used for grace period
  - Publication of examinations
  - Intervening rights
  - *Inter partes* reexamination – third parties can submit prior art and comment, but creates estoppel in later litigation.

Patent reform - further reducing the differences

- Patent Act of 2005, H.R. 2759 – Bill introduced June 2005 after subcommittee draft in April, 2005
  - US to become a “First to file” system
  - Grace period
    - Inventor’s acts only – currently can “swear behind” any prior art
    - Definition of “effective filing date” to change if EPO and Japan enact similar provisions – currently only US filing stops grace period from running
  - Duty of Candor –
    - Inequitable conduct no longer a defense in litigation.
    - USPTO to determine issue. Third parties also bound by duty of candor/disclosure.
  - Post grant opposition – 9 months after issue, 6 months after notice of infringement
  - Injunctions/damages
    - Injunctions no longer automatic – balance test
    - Reasonable royalties based on “inventive contribution” to the entire product
  - Best mode requirement eliminated
  - Assignees can file in their own name
  - Eliminate 102(d) patent bar – patented in a foreign country on application filed more than 12 months before US application. Seen as unduly prejudicing foreign inventors

Patent reform, Industry reaction

- Concerns raised by biotech and software industries
- New Bill introduced in July. Drops certain provisions
  - Injunctions
    - Seen as eroding valuable protection
  - Opposition proceedings
    - Not meant as a substitute for litigation
    - Work-load on the PTO
- New Bill added provisions on venue in patent cases / apportionment of damages

Patent reform, Industry reaction, cont…

- "Coalition Print" – proposal by major US corporations September 1
  - Focuses on Venue / Damages provisions
- Other proposals
  - "English rule" regarding court costs

    -Not receiving much support

Patent reform – likely outcome

- Long process
  - Still in committee
  - Vote in HR
  - Committee hearings in Senate
  - Vote in Senate
  - Sign by President
- Some change is likely, based on what has NOT received much attention/debate
  - First to file
  - Grace period
  - Best mode
  - Assignee as applicant
  - Duty of candor
- Likely to see changes that harmonize patent law / reduce burden on applicants without increasing burden on the PTO

Disappearing differences in biotech

- US traditionally more liberal in granting biotech patents
- Applications for EST's – several were filed in US, while the EPO standard for "Industrial applicability" limited the chances for such applications in Europe
- Recent changes
  - Utility guidelines – a heightened standard for biotech
    - Credible – generally accepted or provable utility
    - Specific – utility shown is specific for the claimed invention, not general to all inventions of the same type
    - Substantial – "real world use"

In re Fisher, Sept 7, 2005

- Claimed 5 EST's corresponding to genes expressed by maize plants, but did not know structure or function of the genes or proteins encoded by those genes
- Applicant listed seven "utilities" for the EST's
  - Could serve as a molecular marker for mapping maize genome
  - Useful in measuring the level of mRNA in a tissue sample
  - Providing a source of primers for use in PCR
  - Identifying the presence or absence of polymorphisms
  - Isolating promoters via "chromosome walking"
  - Controlling protein expression
  - Locating genetic molecules of other plants and organisms
- USPTO rejected the claims for lack of utility

In re Fisher, cont

- Court affirmed the rejection for lack of utility
- Several academic institutions and pharmaceutical companies filed *amicus* briefs in support of USPTO
- Court held that the EST's had no "substantial" utility
  - No present "real word" value to the public – simply the subject of further research since structure and function of underlying genes unknown
  - The EST's are not the end in themselves, but merely tools along the way in a search for a practical utility – would be a "hunting license" to find a real utility later
  - Similar to *Brenner v Manson:* process for making a compound having no know use was unpatentable
- No "specific utility" – several of the uses can be said to apply to any EST, not these specific 5 EST's
- Dissent – Court has improperly applied a higher utility standard for biotech applications than other "research tool" inventions such as microscopes etc. Argues that the court improperly made a value judgment that the disclosed utility was not "important enough"
- *In re Fisher* can be seen as approaching the "Industrial applicability" standard of Europe in biotech applications