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Maskus conclusions

- No reason to shift to "first to invent"
- Patent term for inventions in medicine and biotechnology – allow for regulatory delay
- Do not shift toward recognition of broad claims
- Do not shift to US standard on "burden of proof" in re-exam and litigation
- Special patent court, but with a slightly different weight
- Competition-based approach to regulating the exercise of patent rights

The Issues

- The political economy problem
- The harmonization problem
- Some information about the European post-grant opposition process

Political economy of IP

- IP laws are mostly national
- Competition and innovation are global
- Strengthening IP protection (somewhat) like tax competition:
 - Net benefit for one country, but
 - Lower social welfare if all countries adopt stronger IP
- Substantial asymmetries across countries, due to market size and the degree of spillover (language, trade and FDI)
- The "game" probably has "prisoner's dilemma" type characteristics

Benefits of stronger IP protection in one country

- National
 - Incentives for innovators => more local R&D
 - Increases potential local spillovers from R&D
- International (externality)
 - Increases global incentives for innovation (larger for larger developed economies)
 - To be kept in mind: actual outcomes depend strongly on relative costs and productivity – limits free movement of R&D.

Costs of stronger IP protection in one country

National

- Higher prices due to monopoly power
- Raises the cost of follow-on innovation => may reduce local R&D via increasing transaction costs – this effect can be large in cumulative technologies (see Hall and Ziedonis 2001)
- International (externality)
 - Relative incentive for innovation reduced elsewhere (effect larger if country is a larger developed economy)
 - Cost of follow-on innovation by those in other countries increased (effect larger if country is a larger developed economy)

Harmonization

- Difficult to achieve
 - Problems of the community patent (failure in March at Stockholm) in spite of near-universal demand by European business
 - Involves extensive change to national systems (e.g., litigation harmonization across legal systems with differing origins)
 - Spain and Portugal "their languages and national traditions are being overlooked."
 - "Each year, the EU corporate sector pays the US \$8B in patent royalties while the US pays the EU only \$3B."
- Tends to increase rather than reduce protection, due to stakeholder lobbying and the difficulties of taking rents away from voters
 - TRIPS, pharmaceuticals, and less developed countries
 - European database directive and U.S. measures

Controversies over stronger IP protection

- Subject matter
- Inventive step (non-obviousness)
- Prior art
- Broad claims (and the quality of description in the patent – is it enough information for someone skilled in the art to do it)

The last 3 might be addressed by post-grant reexamination or opposition.

Post-grant challenges: US vs EU

- United States patent challenges
 - Reexamination post-issue (life of patent)
 - Litigation for validity or infringement
- ◆EU (EPO) patent challenges
 - Post-grant opposition (within 9 mos.)
 - Litigation for validity or infringement in national courts

United States (USPTO)

- Secrecy throughout the period that patent application is pending (until this year, now 18 months)
- Re-examination after issue limited to validity questions; examiners are final arbiters.
 - Administrative ex parte proceeding—requester role limited to application, and to
 - Right to receive notice of decision
 - Right to receive copy of patentee's response
 - Right to file rejoinder to that response
 - Relatively large filing fee (\$2,500)
 - Admissible evidence limited—prior patents and publications
 - Regulatory hurdle: "Substantial question of patentability"
 - Barrier to pursuing litigation ex post
- Lesson: significant limitations and not used much

European Patent Office (EPO)

- Publication of application 18 months after application date
- Opposition validity only
 - Administrative adversarial proceeding initiated by any third party
 - Time limit: Must file within 9 months of patent grant
 - Patent may be challenged on any of the grounds of patentability—novelty, inventive step, industrial application
 - No limits on the kinds of evidence admissible
 - Examiners and then administrative judges (on appeal) hear challenge
 - Much lower cost than litigation, but slow.

Institutional Differences: Outcomes

- Europe
 - Probability of opposition: 4 to 8%
 - Opposition lag after application:
 - median 5.5 years
 - 90% by 7.5 years
 - Opposition results
 - 33% of patents are revoked in full (Merges, 1999)
 - Our (GHHM) pharma/biotech data confirm these
 - 25% of patents are confirmed in full
 - 40% of patents are amended
 - 34% of patents are revoked in full

Institutional Differences: Outcomes

- United States
 - Probability of re-examination: 0.2%
 - Re-examination lag after application:
 - median 3.5 years
 - 90% by 11.5 years
 - Re-examination results
 - Stacy 1997
 - 28% of patents are confirmed in full
 - 59% of patents are amended
 - 13% of patents are revoked in full
 - GHHM 1980-1999
 - 33% of patents are confirmed in full
 - 46% of patents are amended
 - 21% of patents only have claims cancelled

Conclusions (besides those already stated)

- Need a model of the interaction of IP regimes in different jurisdictions
- Keep an eye on the U.S.
 - backlash to subject matter expansion and prior art problems (double exams for business method patents)
- Difficult to put the genie back in the bottle, so go slow on stronger rights