

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 **Toronto IP Conference** 5/25/01 7

Controversies over stronger IP protection



- 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

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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