Eidgenössisches Institut für Geistiges Eigentum
Institut Fédéral de la Propriété Intellectuelle
Istituto Federale della Proprietà Intellettuale
Swiss Federal Institute of Intellectual Property

CSIC/OECD/OEPM Conference

Research use of patented inventions

Madrid, 18-19 May 2006

A new research exemption for Switzerland:

Empirical findings and the draft revision of the patent law

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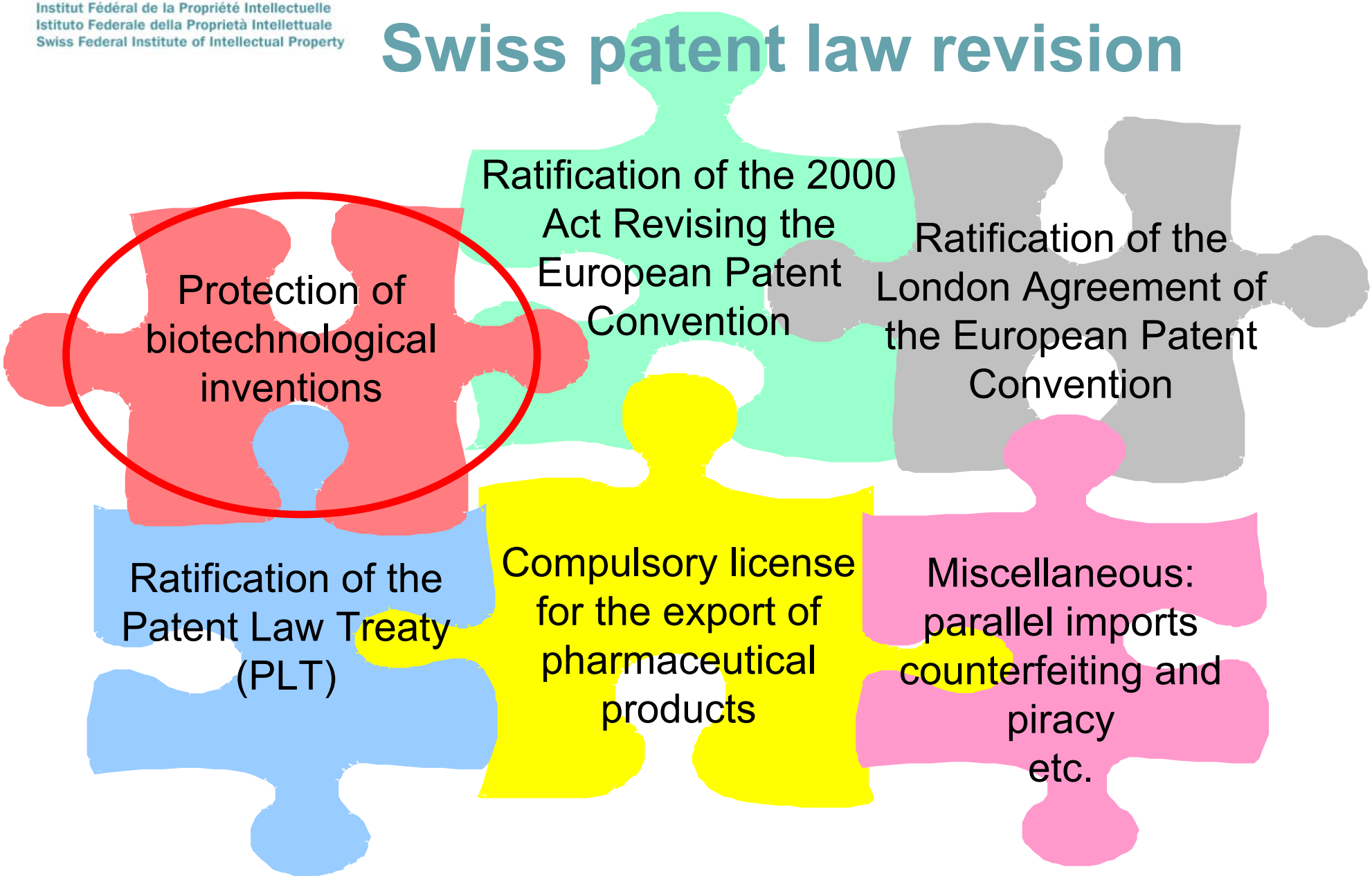
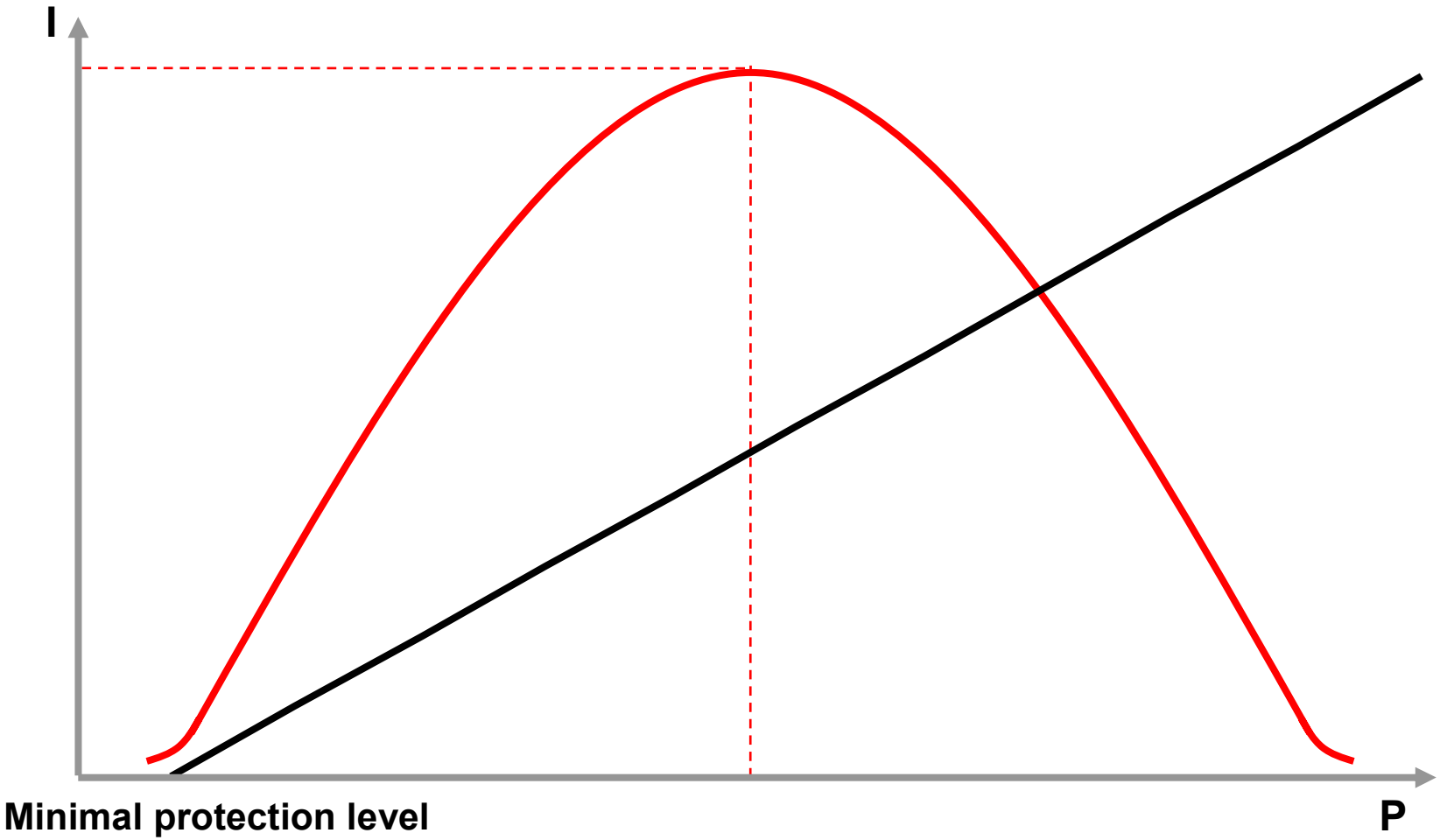
Swiss patent law revision



Policy Issues with Biotech Patents

1. **Exclusions of patentability for reasons of ordre public and morality**
2. **Patenting of gene sequences**
3. **Research/experimental use exemption**
4. **Research tool patents**
5. **Patenting of diagnostic tests**

Patents as a Policy Measure
Protection (P) *vs.* Innovation (I)

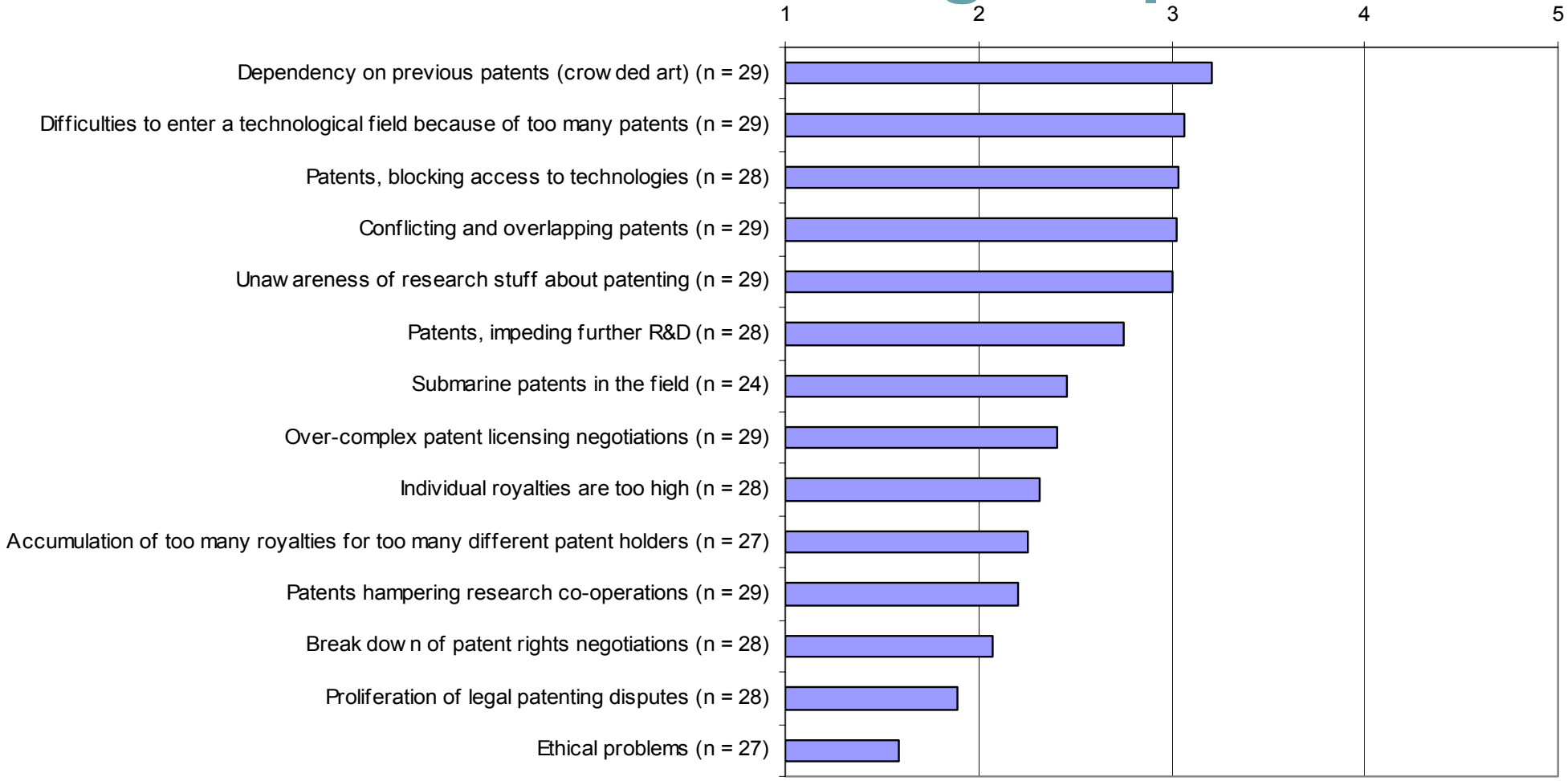


Limitation of Research?

- **Limitation of upstream inventions?**
- **‚Anti-commons‘**
- **Patent thickets**
- **Royalty stacking**
- **Abusive monpoly position (Myriad)**

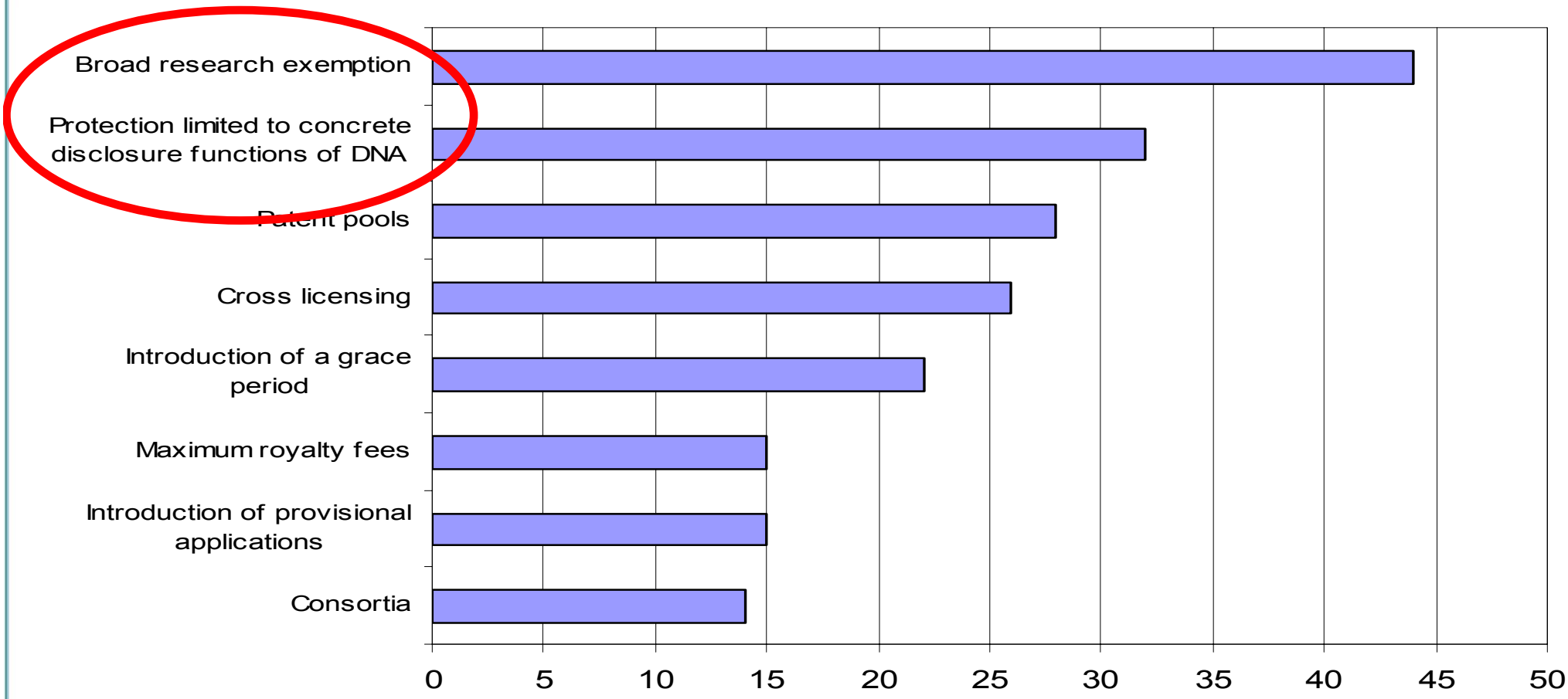
Empirical evidence?

Problems with gene patents



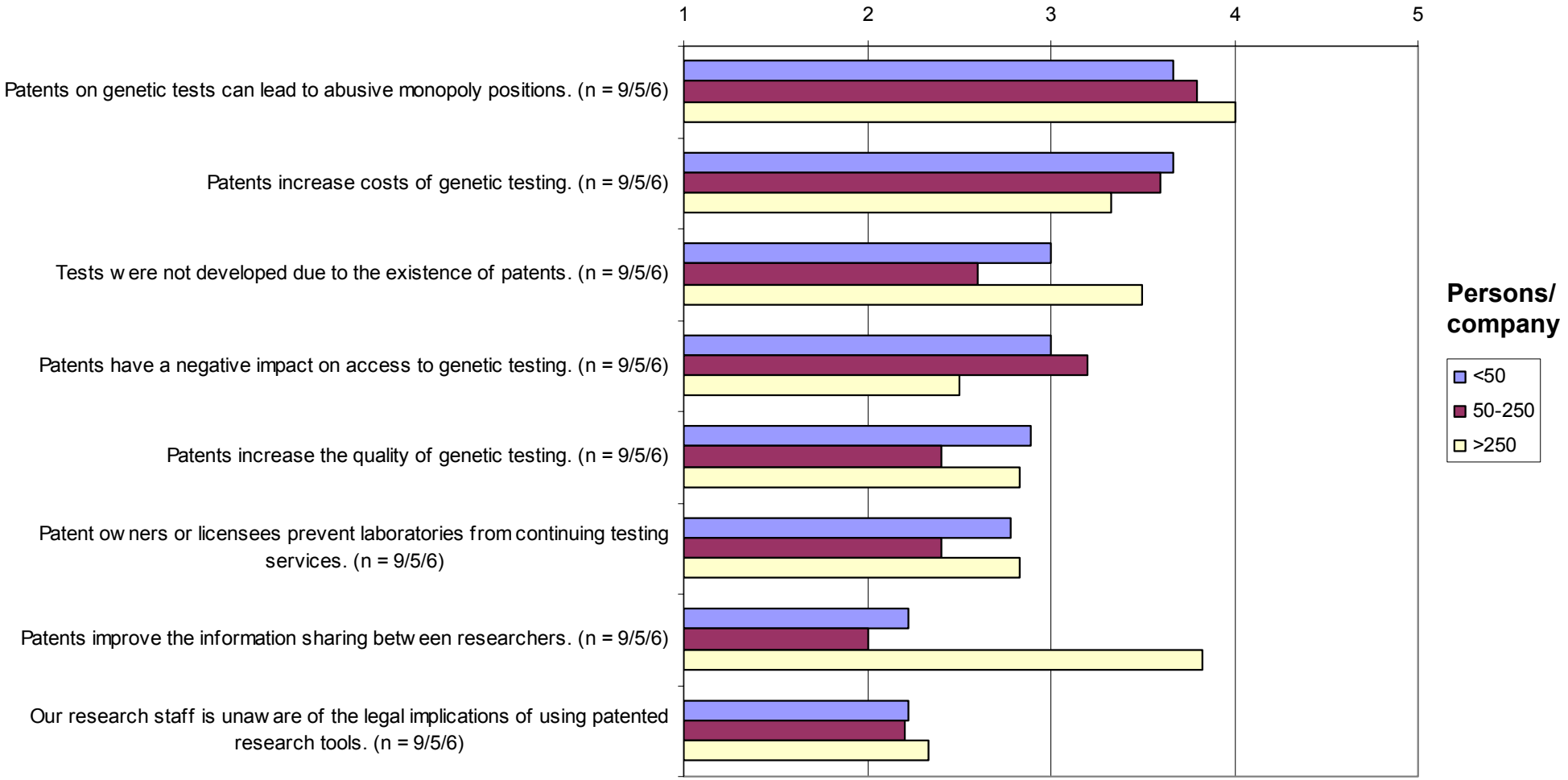
CH Survey: 8.2 Extent of Experience of Problems with DNA Patents, Fig. 34 (1=never, 5=very often)
(http://www.ige.ch/E/jurinfo/documents/j10005e.pdf)

Gene patents: Proposed remedies



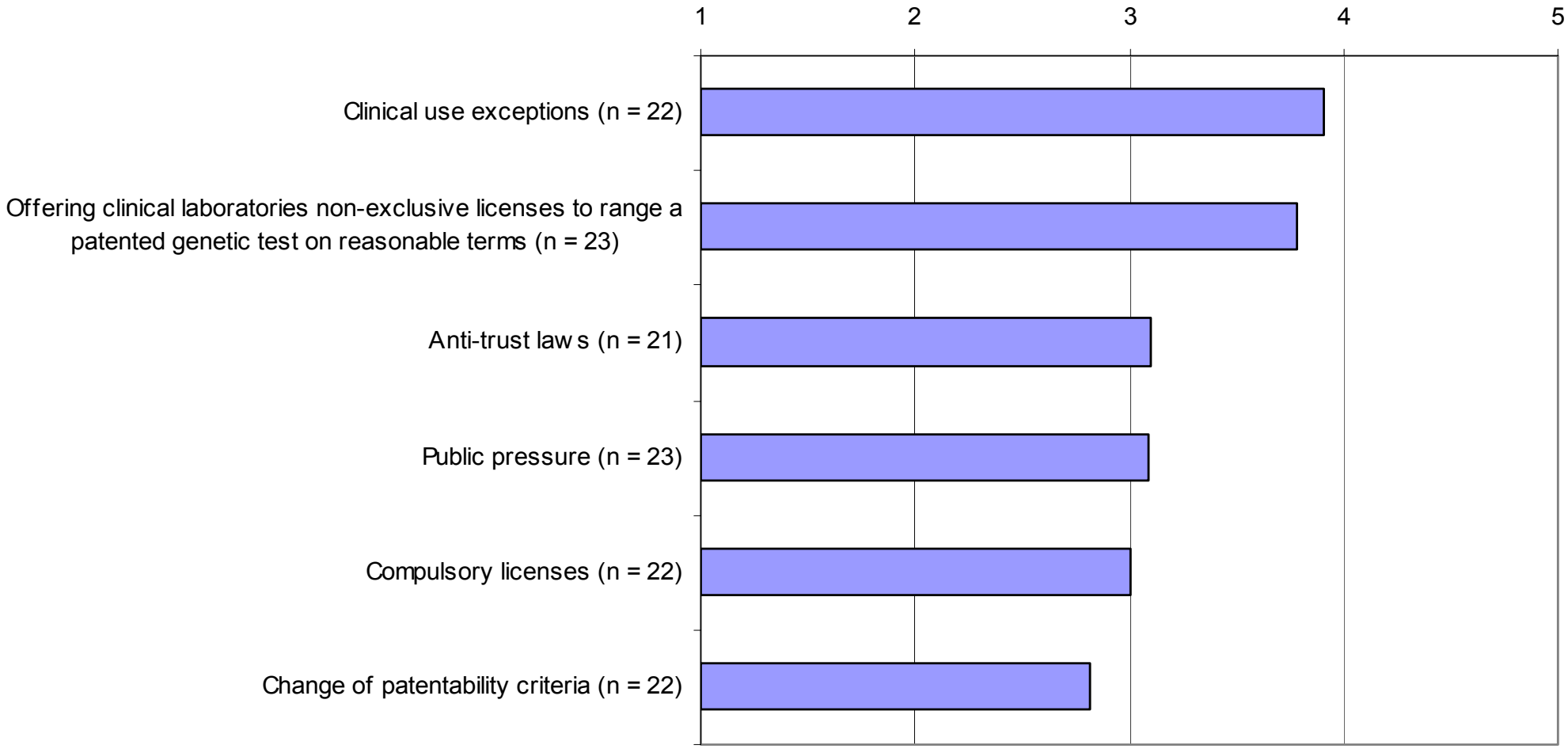
CH Survey: 8.2 Remedies, Fig. 35 (named as many times as effectively to ...)
(http://www.ige.ch/E/jurinfo/documents/j10005e.pdf)

Problems with patents on genetic tests



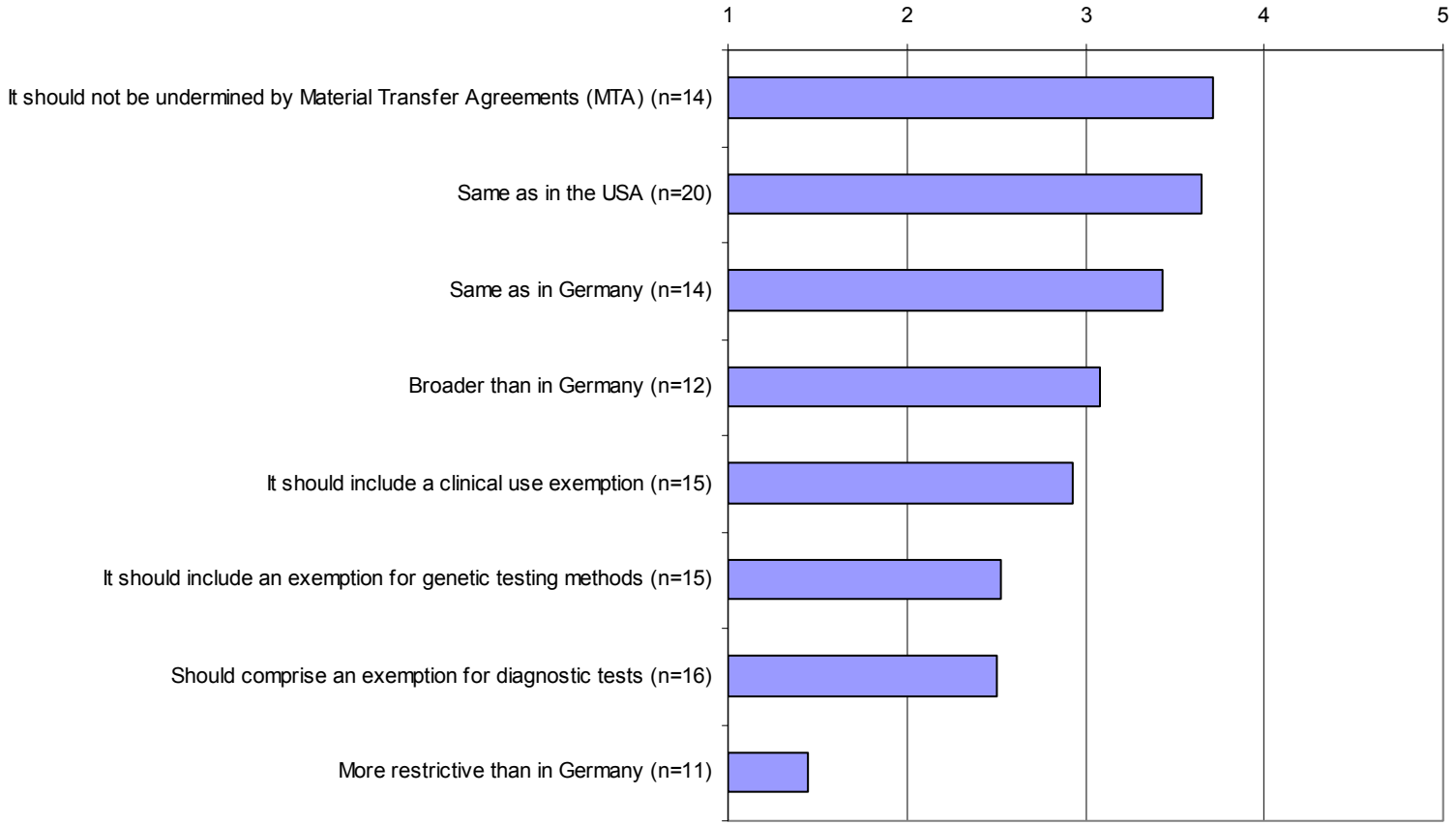
CH Survey: 9.2 Genetic testing, Fig. 42 (1=very low, 5=very often) (http://www.ige.ch/E/jurinfo/documents/j10005e.pdf)

Patents on genetic tests: Proposed remedies



CH Survey: 9.2 Genetic testing, p. 60 (1=very low, 5=very often) (http://www.ige.ch/E/jurinfo/documents/j10005e.pdf)

Research Exemption



CH Survey: 8.2 Research Exemption, Fig. 37 (1=never, 5=very often)
(http://www.ige.ch/E/jurinfo/documents/j10005e.pdf)

Swiss Proposal for a research exemption

Art 9: general exemptions from patenting

Art 9 1a: Private use for non-commercial purposes
Art 9 1b: **Research and trials where the invention is the object of research**
Art 9 1c: Use of the invention for teaching purposes
Art 9 1d: Use of biological material for the purpose of breading or for developing a plant variety
Art 9 1e: Biological Material produced randomly or technically not avoidable in the agricultural sector

Research/experimental use exemption

When do you need a license to use patented inventions for research purposes?

- All research (commercial or not) free - if aimed at gaining new knowledge about subject matter of the invention
- "Bolar exemption": Use of the invention to obtain the authorisation of a pharmaceutical product, e.g. through
  - Clinical trials,
  - Production of specimens, BUT
  - Production of the new drug only after expiration of the patent (= no stockpiling)

Limits of research exemption

Invention must be the object and not the instrument of research:

- **no free use of „research tools“, such as polymerase chain reaction)**
- **if instrument = licence needed**

Access guaranteed through legal license (draft Art. 9a):

- **= right to use the research tool for everybody**
- **+ obligation to pay license fee**
- **no agreement = fee fixed by a court**
- **no “reach through” license fees**

Summary

- Patents do matter in biotechnology!
- Theoretical concerns are real!
- But no break-down nor systematic abuse of the patent system
- Problems with Patents on genetic tests
- Possible Remedies:
  - broad research exemption
  - Limitation of the scope of protetion (specific disclosed functions) for DNA patents
  - Single license, compulsory licensing

Policy Conclusions

- Good IP policy is not maximal rights Policy!
- Raise the patenting standard
- Better patenting than secrecy
- Encourage free market solutions
- Compulsory licensing last remedy
- Future work: -research exemption, -non exclusive licensing for clinical laboratories, -use exemption for medical use

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Thank you!

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Info Patent Law Reform:
http://www.ige.ch/E/jurinfo/j100.shtm#a03

Biotech Report:
http://www.ige.ch/E/jurinfo/documents/j10005e.pdf

Summary Article:

Thumm, N. (2005) 'Patents for genetic inventions: a tool to promote technological advance or a limitation to upstream inventions', Technovation, The International Journal of Technological Innovation and Entrepreneurship, Vol 25/12 pp. 1410-1417