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

WHO CIPIH Studies Workshop

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The Patent System – Making it Better

The current Revision of the Swiss Patent Law

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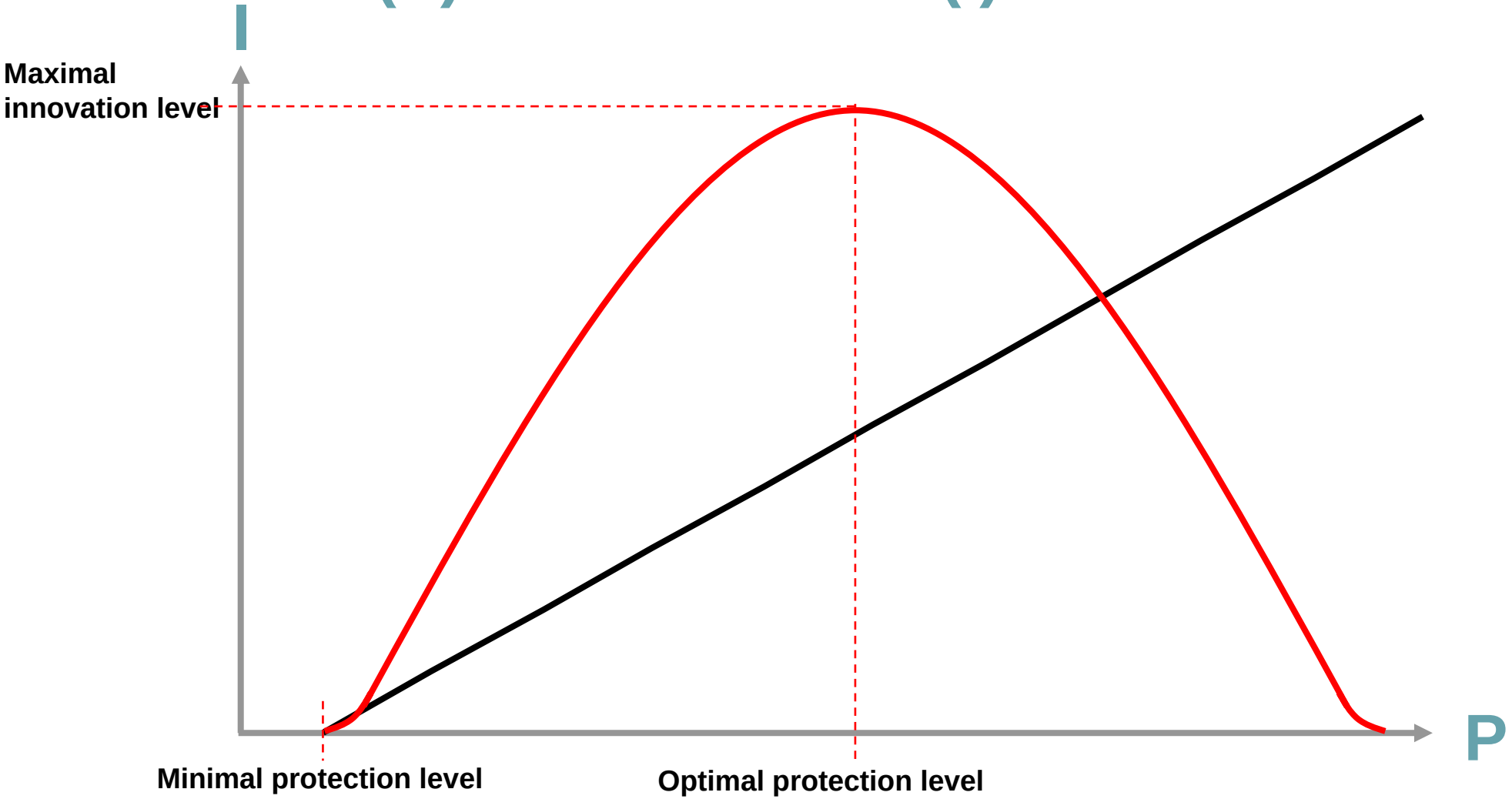
Protection (P) *vs.* Innovation (I)



→**CH Survey: Research and Patenting in Biotechnology** (http://www.ige.ch/E/jurinfo/documents/j10005e.pdf)

Overview

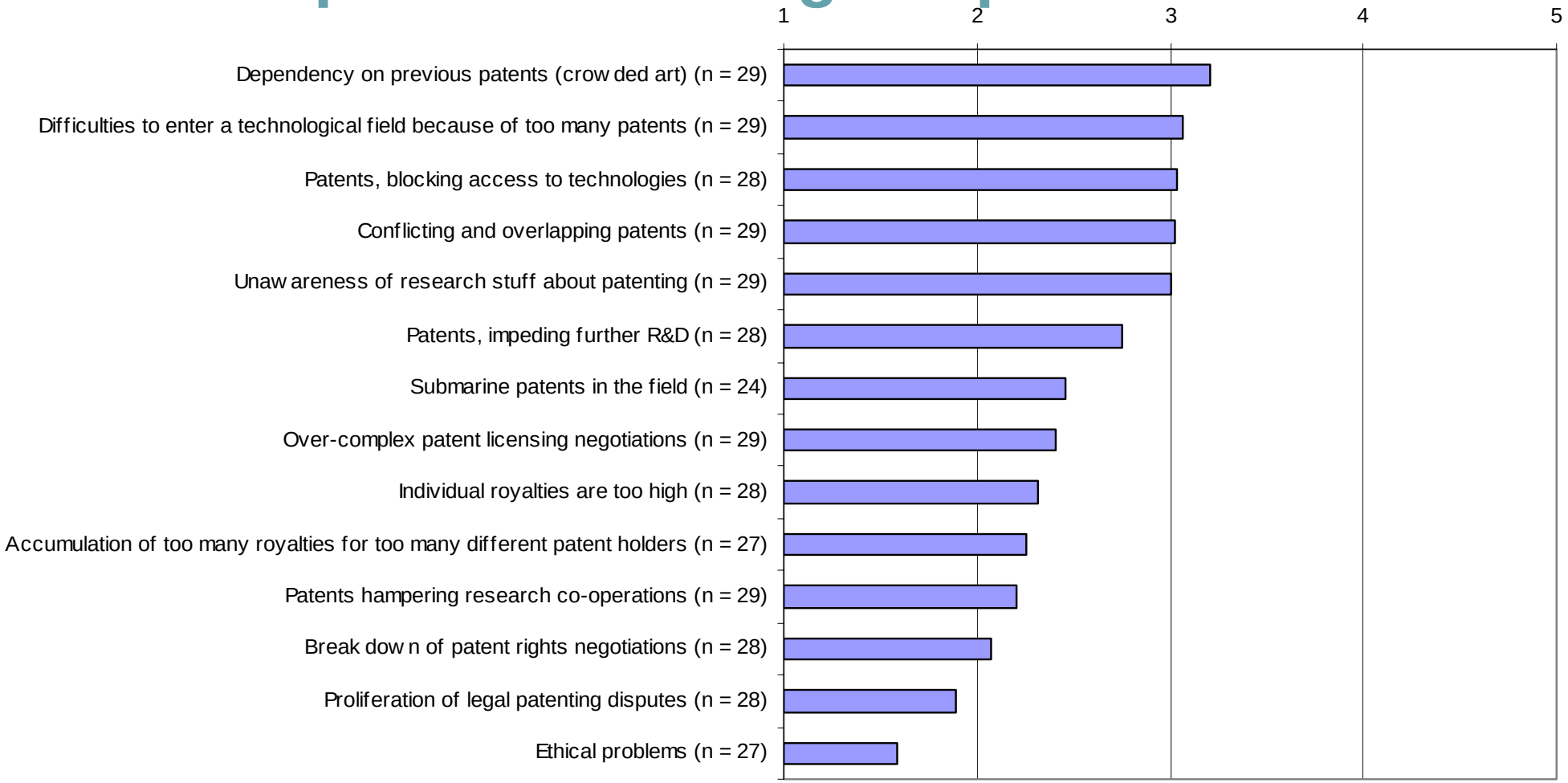
1. **Exclusions of patentability for reasons of ordre public and morality**
2. **Patenting of gene sequences**
3. **Research/experimental use exemption**
4. **Research tool patents**
5. **Patenting of diagnostic tests**

1. Exclusions of patentability for reasons of ordre public and morality

Art. 2(3) Draft CH Patent Law:

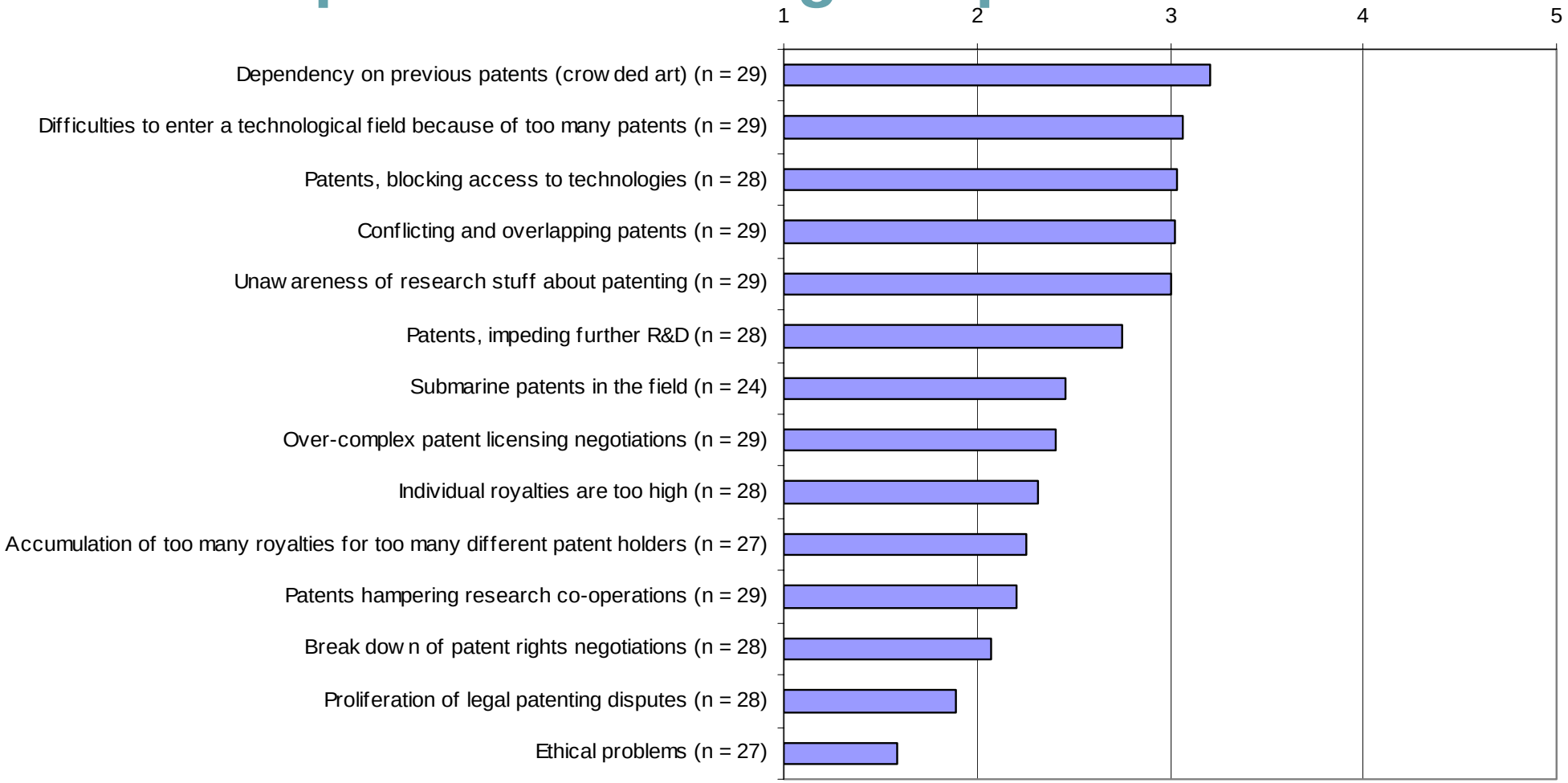
- **violation of human dignity and disregard of the dignity of plants and animals**
- **illustrative list of inventions contrary to ordre public**
  (**in force since 1st March 2005 / proposed amendments**):
  - (reproductive and therapeutic) **processes for cloning human beings**
  - **processes for producing hybrids or chimeras** (but not transgenic animals)
  - **processes for human parthenogenesis**
  - **germ line therapy** (but not somatic gene therapy)
  - **unmodified human embryonic stem cells**
  - **uses of human embryos** (non-medical uses)
  - **processes for genetic modification of animals likely to cause suffering**

2. Main problems with gene patents



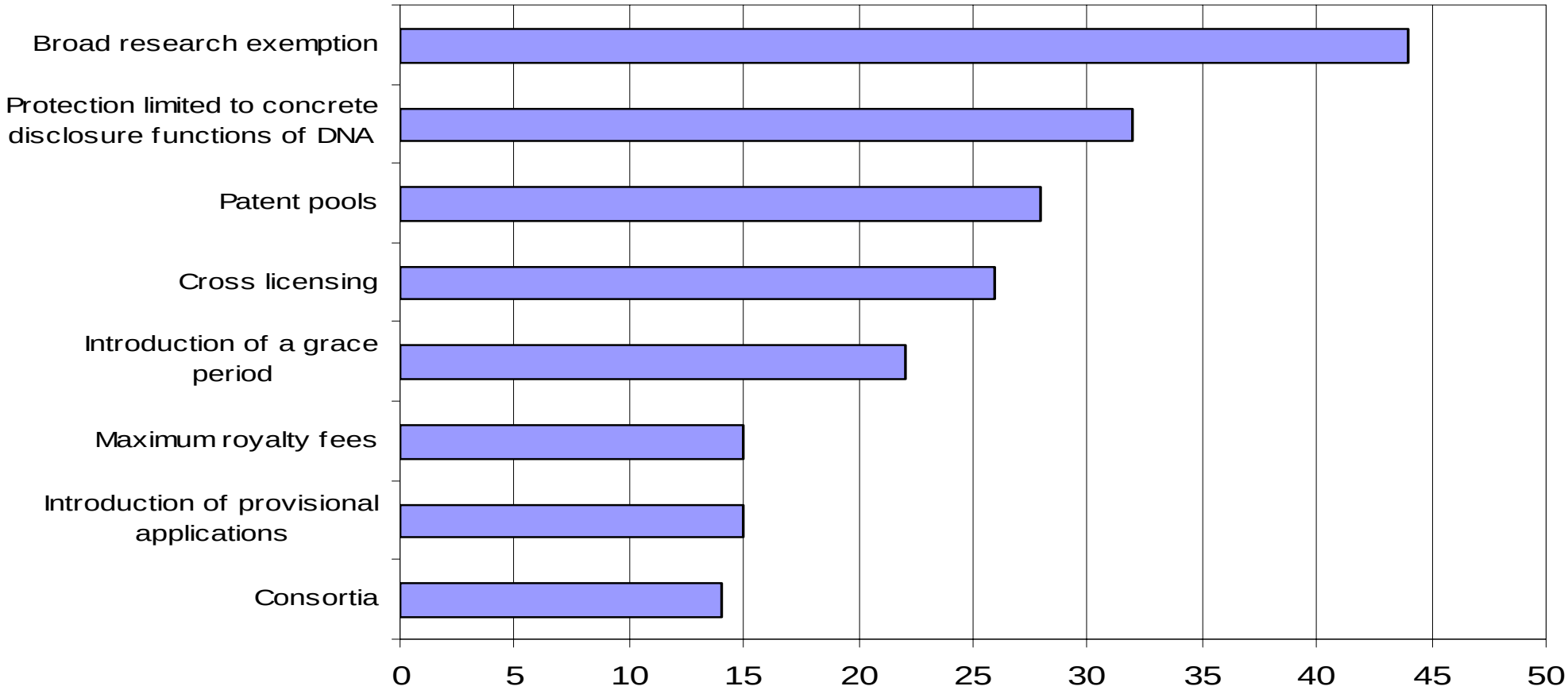
CH Survey: 8.2 Extent of Experience of Problems with DNA Patents, Fig. 34 (1=never, 5=very often) (http://www.ige.ch/E/jurinfo/documents/j10005e.pdf)

2. Main problems with gene patents



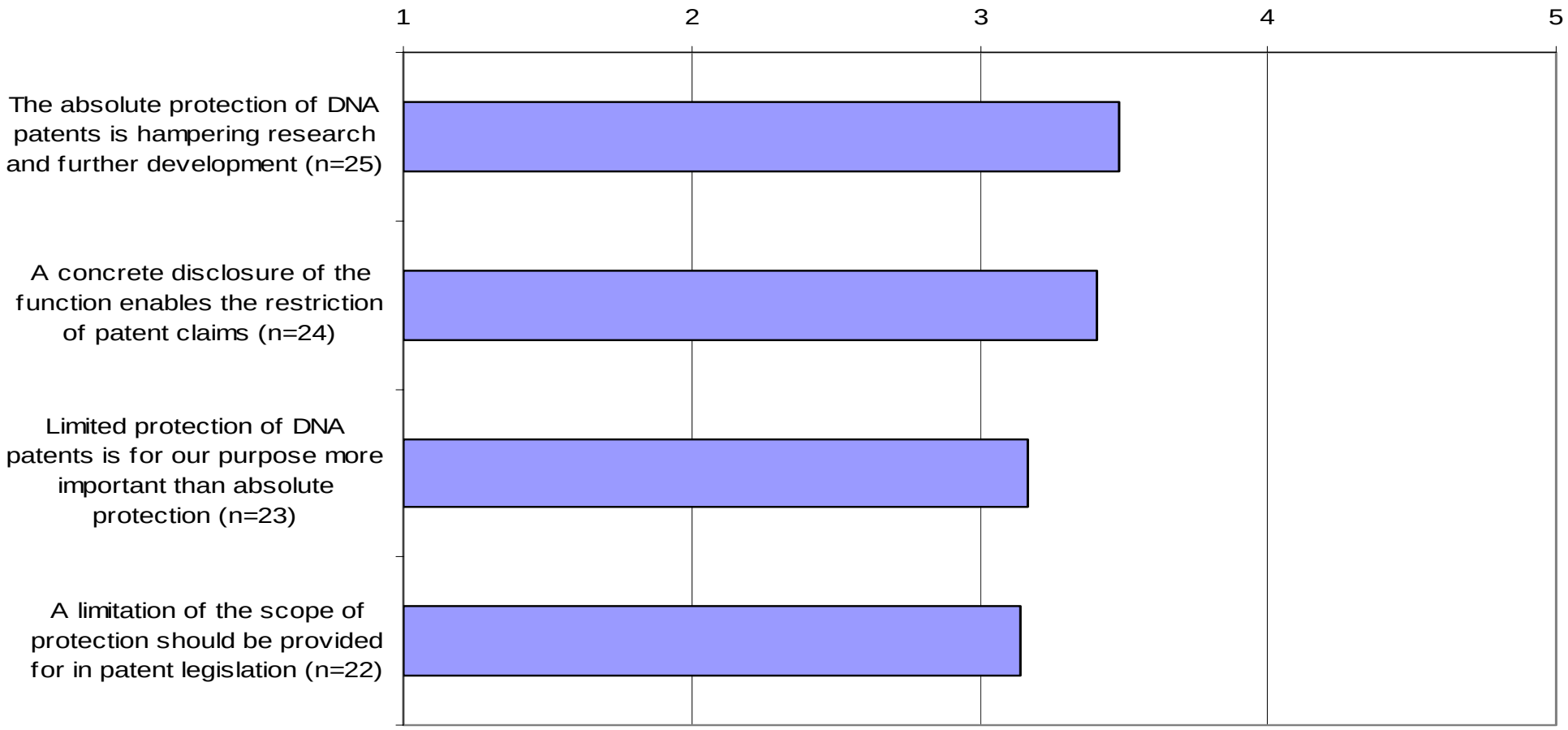
CH Survey: 8.2 Extent of Experience of Problems with DNA Patents, Fig. 34 (1=never, 5=very often) (http://www.ige.ch/E/jurinfo/documents/j10005e.pdf)

Gene patents: Proposed remedies



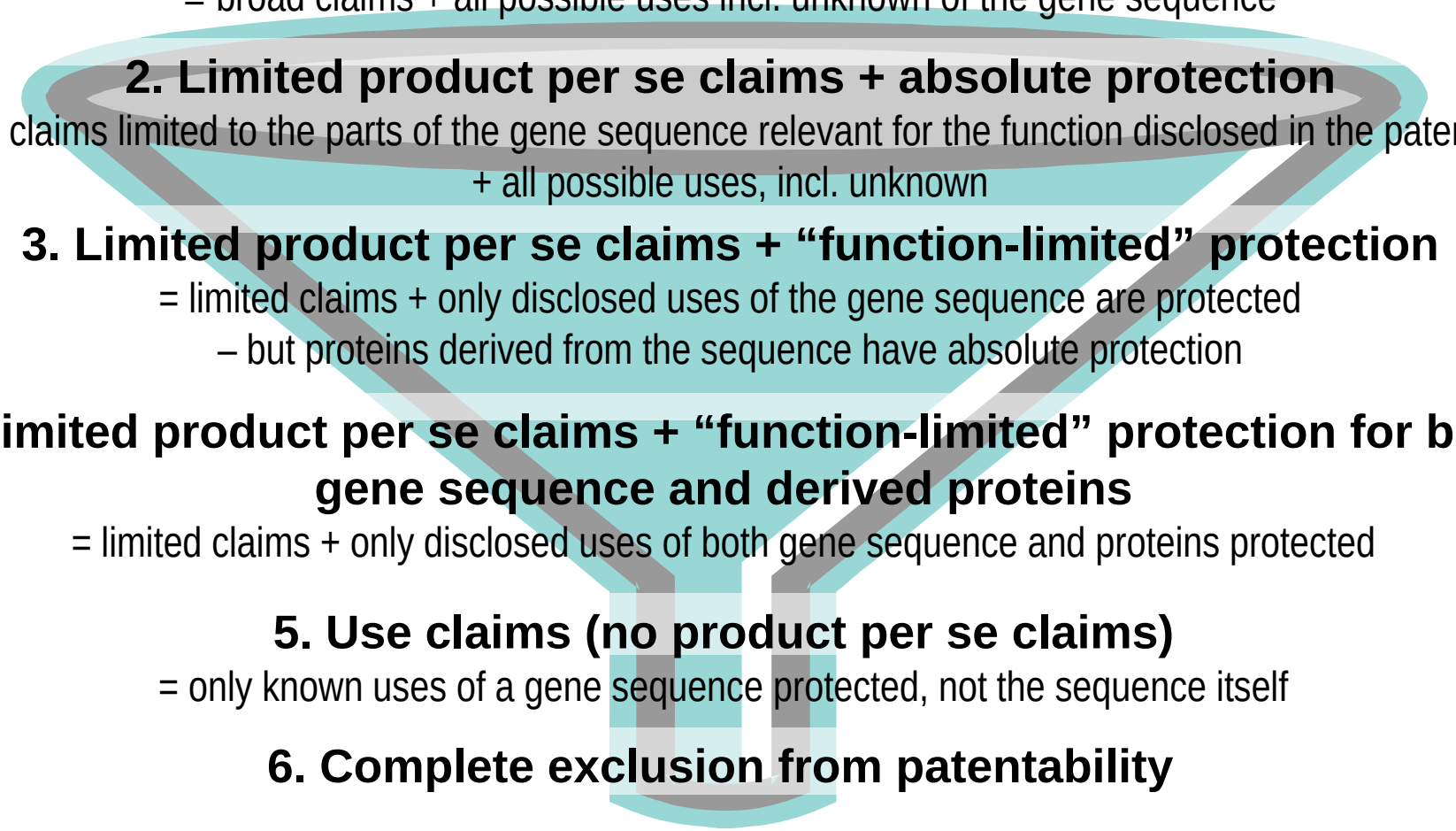
CH Survey: 8.2 Remedies, Fig. 35 (named as many times as effectively to ...)
(http://www.ige.ch/E/jurinfo/documents/j10005e.pdf)

Concrete disclosure functions of gene patents



CH Survey: 8.2 Extent of Experience of Problems with DNA Patents, Fig. 39 (1=no agreement, 5=total agreement) (http://www.ige.ch/E/jurinfo/documents/j10005e.pdf)

Options for the scope of gene patents



1. Large product per se claims + absolute protection

= broad claims + all possible uses incl. unknown of the gene sequence

2. Limited product per se claims + absolute protection

= claims limited to the parts of the gene sequence relevant for the function disclosed in the patent
+ all possible uses, incl. unknown

3. Limited product per se claims + "function-limited" protection

= limited claims + only disclosed uses of the gene sequence are protected
– but proteins derived from the sequence have absolute protection

4. Limited product per se claims + "function-limited" protection for both gene sequence and derived proteins

= limited claims + only disclosed uses of both gene sequence and proteins protected

5. Use claims (no product per se claims)

= only known uses of a gene sequence protected, not the sequence itself

6. Complete exclusion from patentability

Scope of protection for genes: Discussion in Switzerland

Art. 8c Draft CH Patent Law:

limited product claims + „function-limited“ protection

- **All processes to make the product are protected** (even if unknown),

  BUT

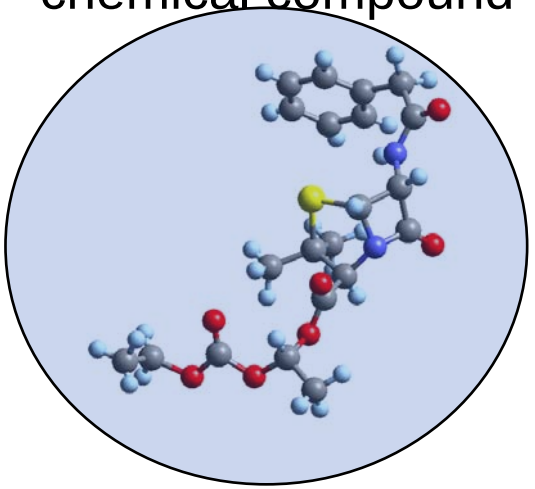
- **claims are limited to the parts of the gene sequence relevant for the function disclosed in the patent and**
- **only the specific functions (uses) of both gene sequence and proteins that are disclosed in the patent application are protected**

= Option 4: Two folded limitation (claims and scope)

Function-limited

Absolute protection

chemical compound



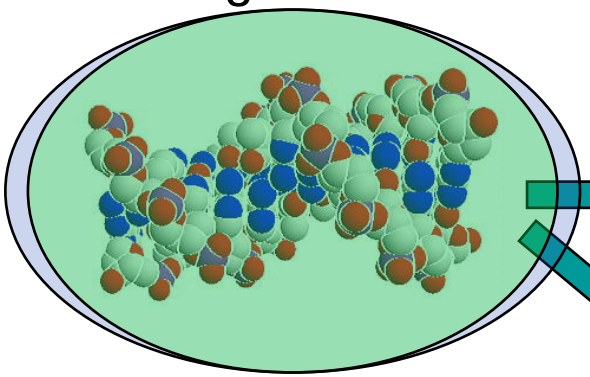
possible uses

A

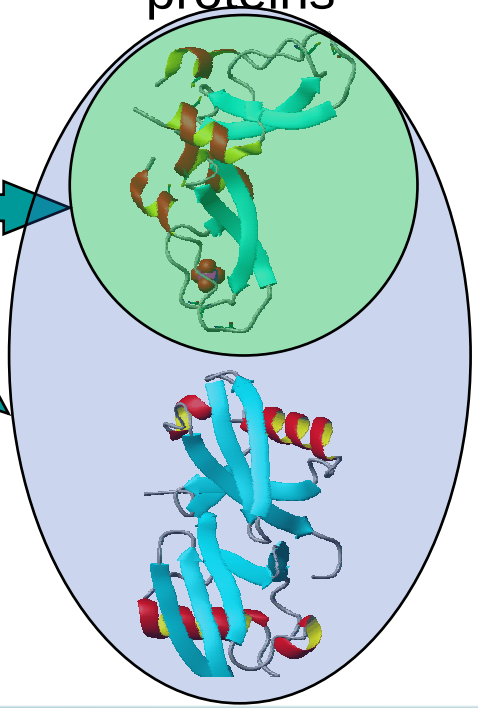
B

C

gene



proteins



Possible uses

A

B

C

D

E

F

Possible consequences for R&D

This means

- research on other functions of the same gene sequence/protein not in conflict with existing patent (outside the scope)
- no mutual dependence of patents
- no monopolies on gene sequences as such
- patents on other functions of the same gene sequence/protein are independent

This triggers

- research on new medical uses/indications

3. Research/experimental use exemption

(Art. 9.1b Draft CH Patent Law)

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**
- **Introduction of "bolar exemption": Use of the invention to obtain the authorisation of a pharmaceutical product = free → use of invention e.g. through**
  - **Clinical trials = possible**
  - **Even production of specimens = possible**

  BUT
  - **Production of the new drug only after expiration of the patent (= no stockpiling)**

4. Limits of research exemption: The issue of research tools

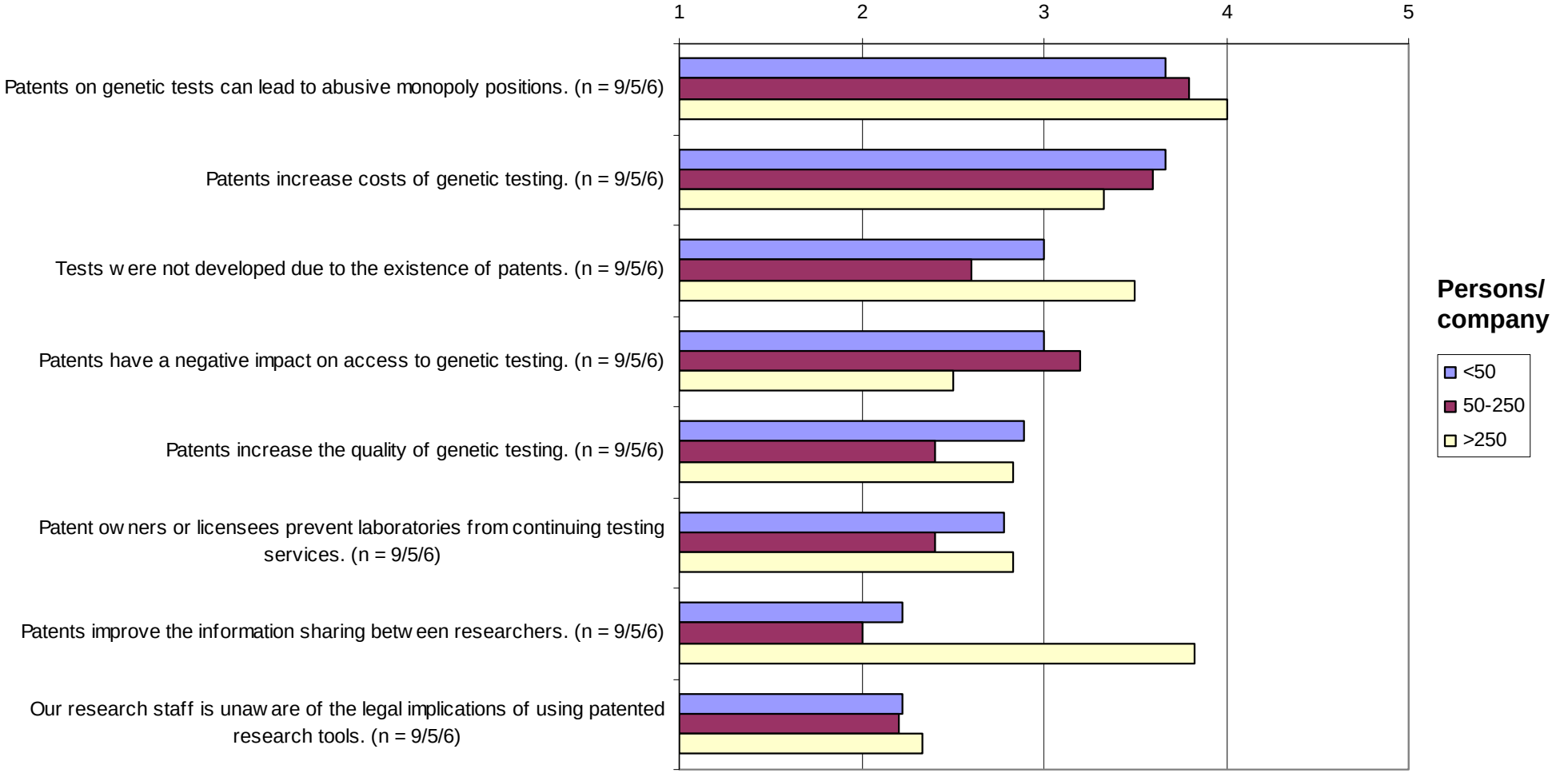
Invention must be the object and not the instrument of research:

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

Solution: Access guaranteed through legal license (Art. 9a Draft CH Patent Law):

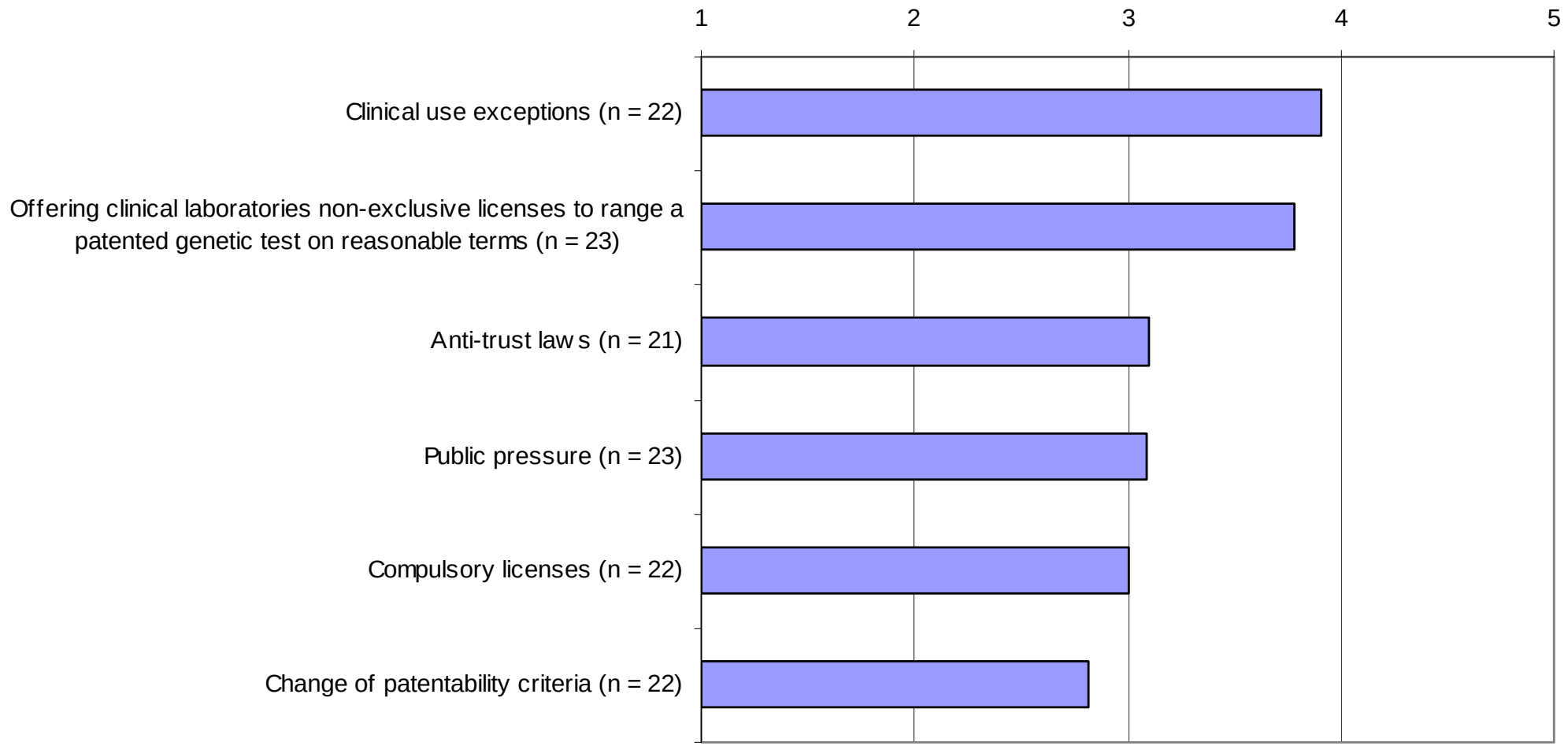
- **= right to use the research tool for everybody**
- **+ obligation to pay license fee**
- **no agreement = fee fixed by a court**
- **no “reach through” license fees**

5. Main 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)

Compulsory license for diagnostic testing

Access to reliable diagnostic methods may be hampered if

- **disease caused by specific gene sequence or single nucleotide polymorphisms (SNPs), and**
- **diagnostic method based on the relevant nucleotide sequence patented**

Art. 40b Draft CH Patent Law provides for a compulsory licence, in case of

- **Anticompetitive behaviour = breach of antitrust law/abuse of dominant position/agreement restricting competition/abusive behaviour**

  (e.g. BRCA1- breast cancer gene)

More information

on the ongoing revision of the Swiss Patent Law, including a preliminary draft, is available on the website of the Swiss Federal Institute of Intellectual Property

http://www.ige.ch/E/jurinfo/j100.shtm#2

Electronic Newsletter:

http://www.ige.ch/E/jurinfo/j201.shtm

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„The patent system adds the fuel of interest to the fire of genius“

Abraham Lincoln