

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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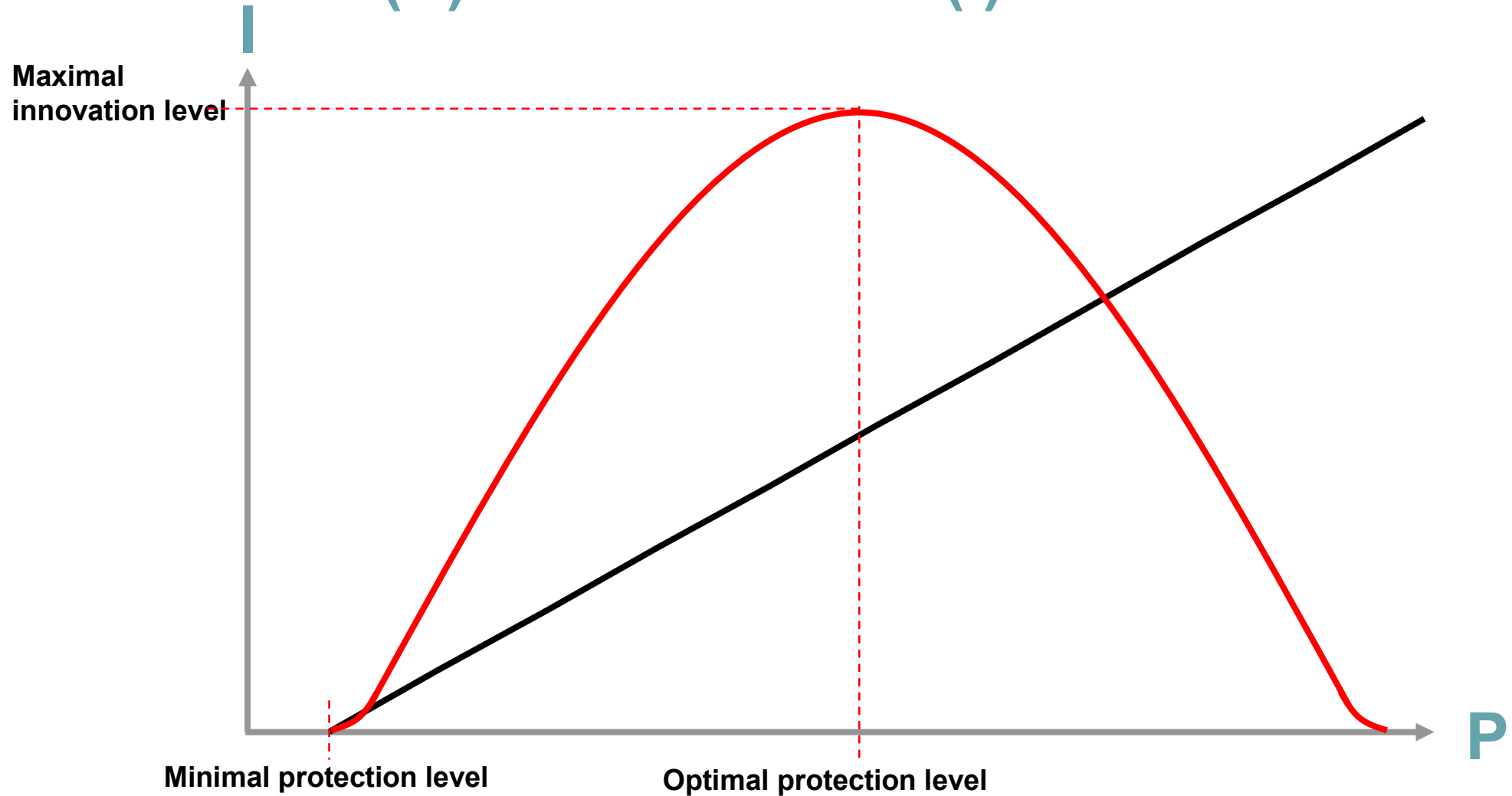
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CH - 3003 Bern



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**



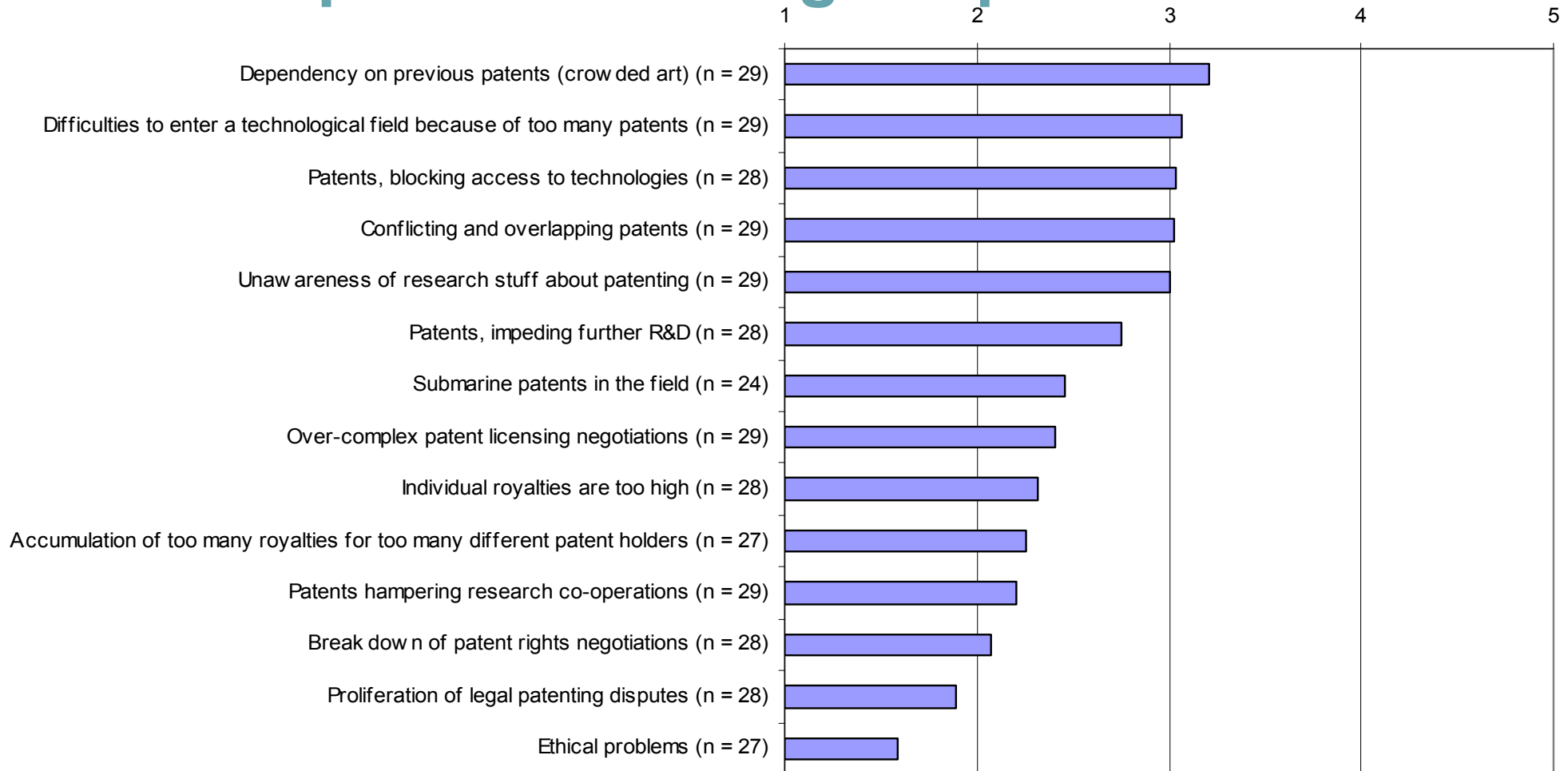
1. Exclusions of patentability for reasons of ordre public and morality

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**



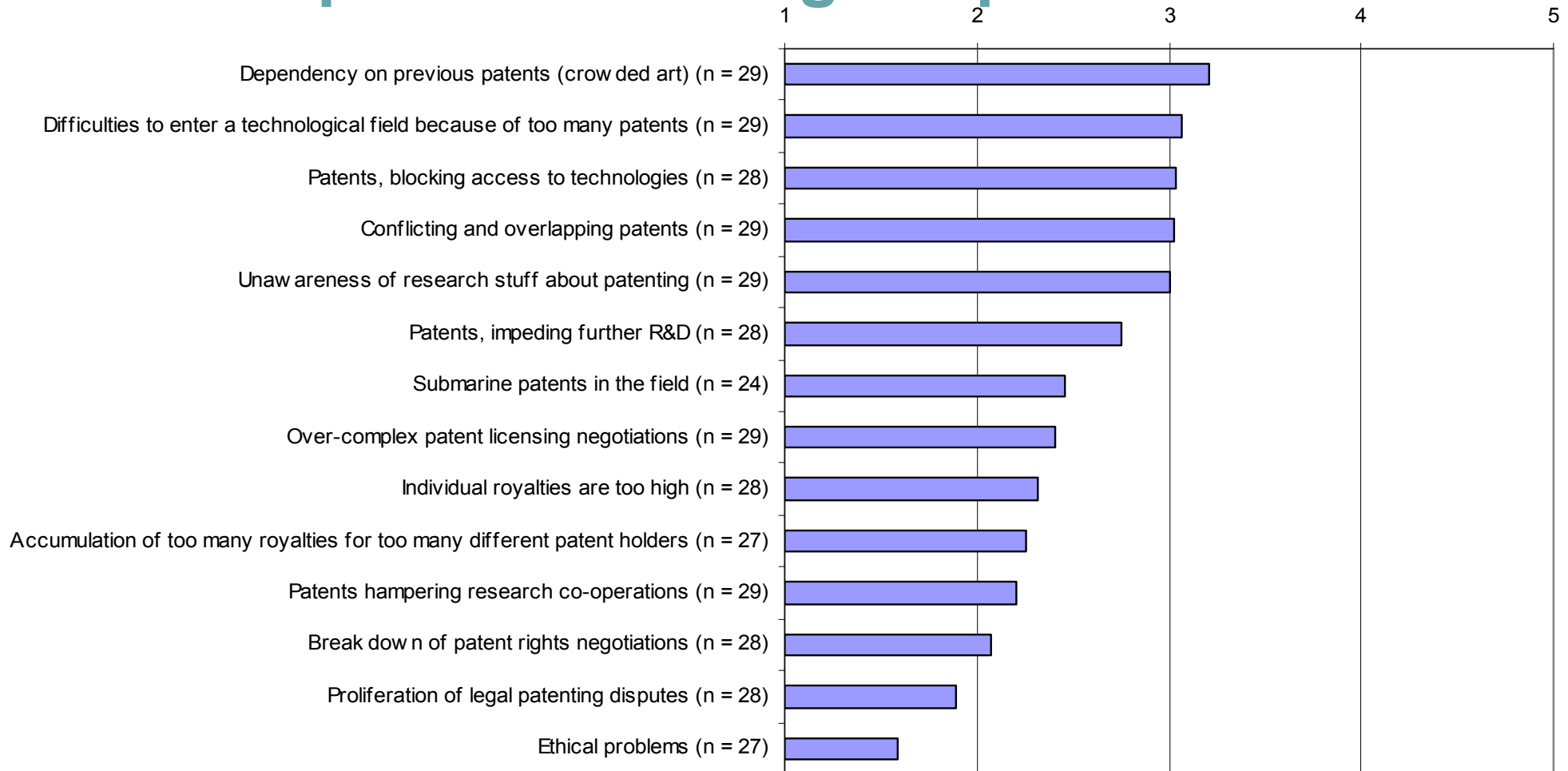
2. Main problems with gene patents



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>)



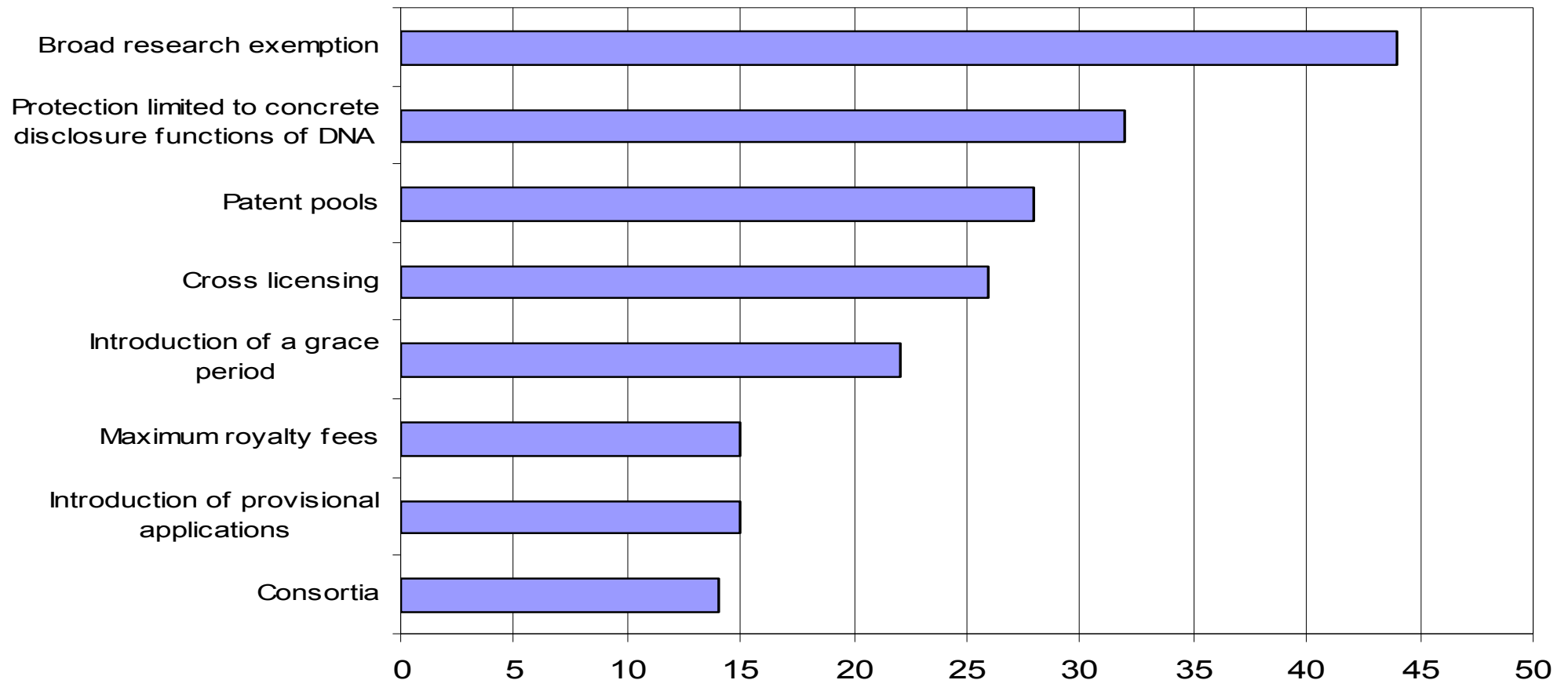
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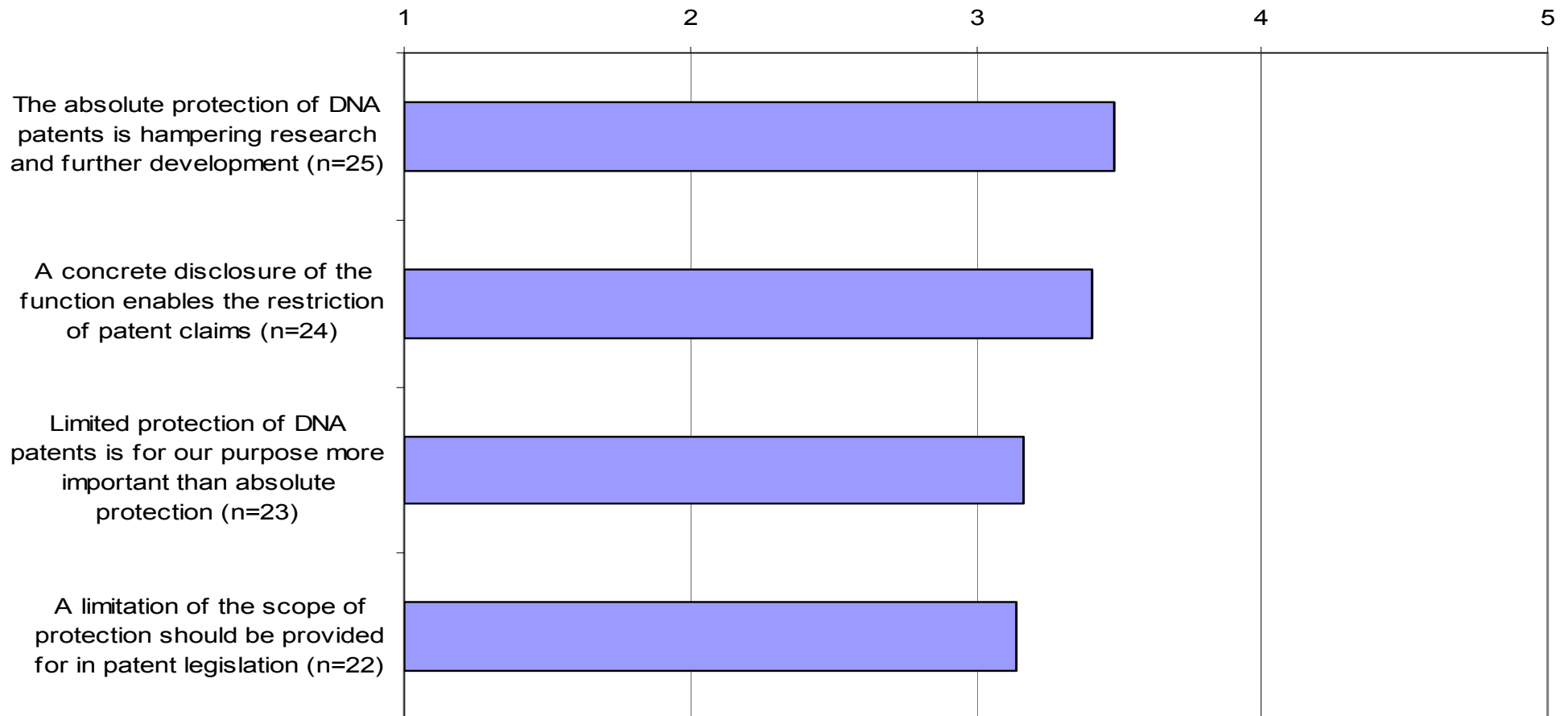
Gene patents: Proposed remedies



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

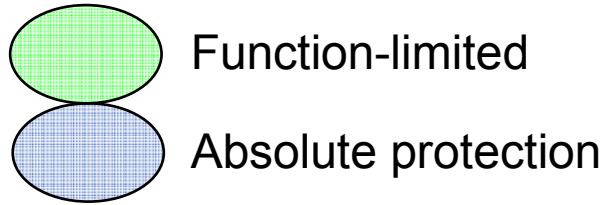
- All processes to make the product are protected (even if unknown),

BUT

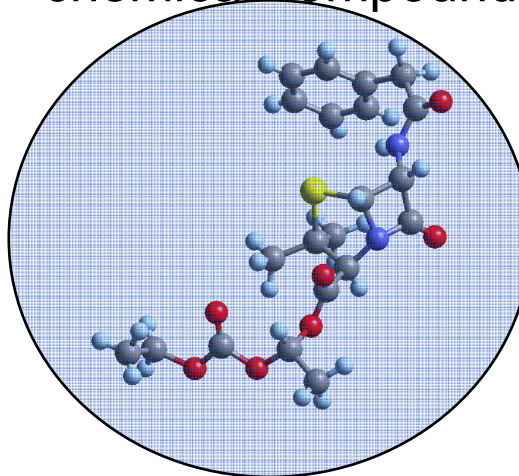
- claims are limited to the parts of the gene sequence relevant for the function disclosed in the patent and
- only the specific functions (uses) of both gene sequence and proteins that are disclosed in the patent application are protected

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

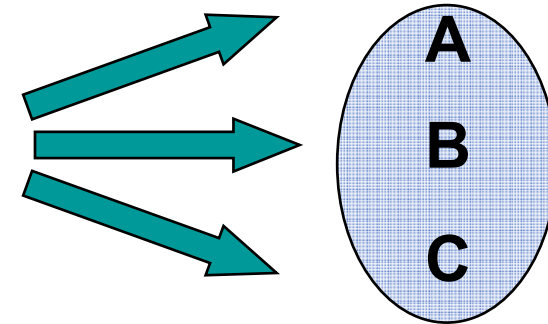




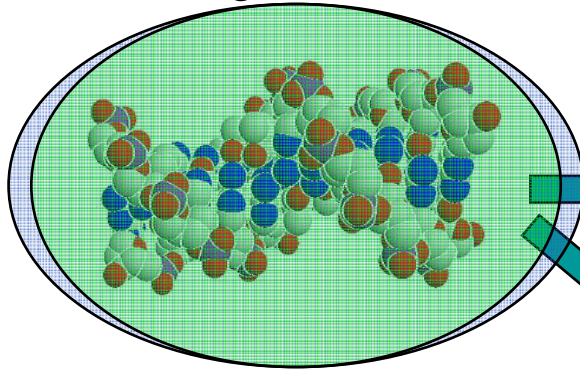
chemical compound



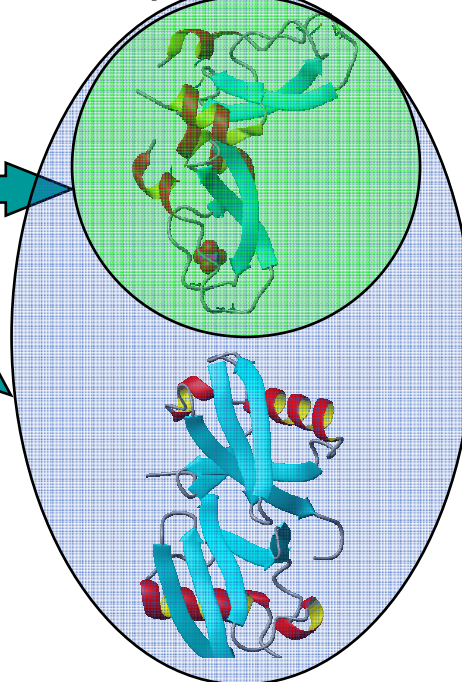
possible uses



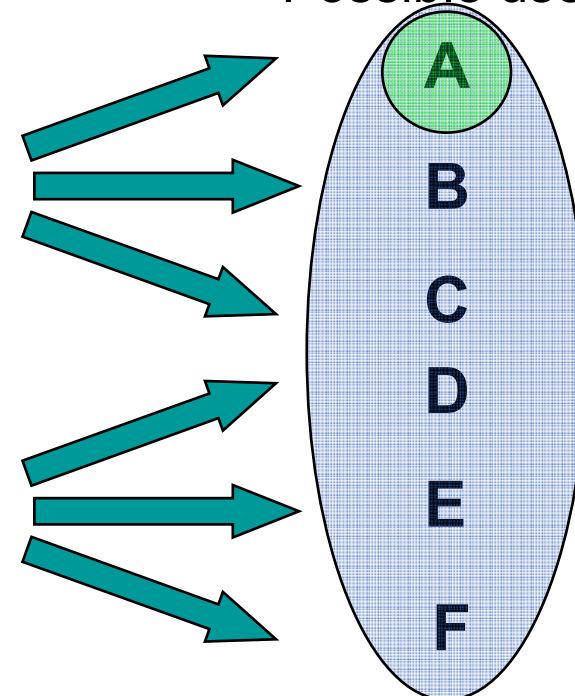
gene



proteins



Possible uses



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:

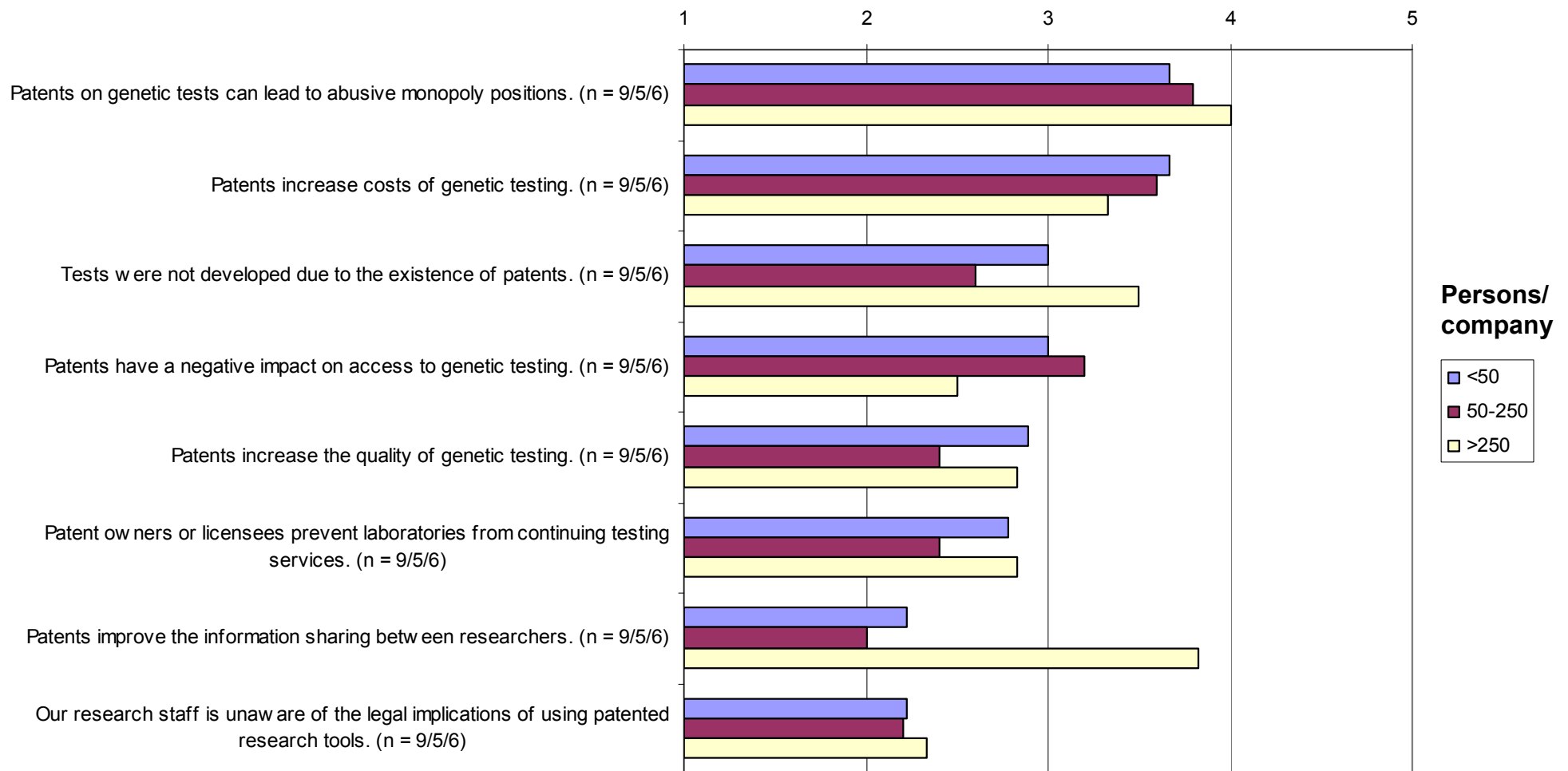
- Problem: no free use of „**research tools**“, (such as polymerase chain reaction)
- if instrument = licence needed

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



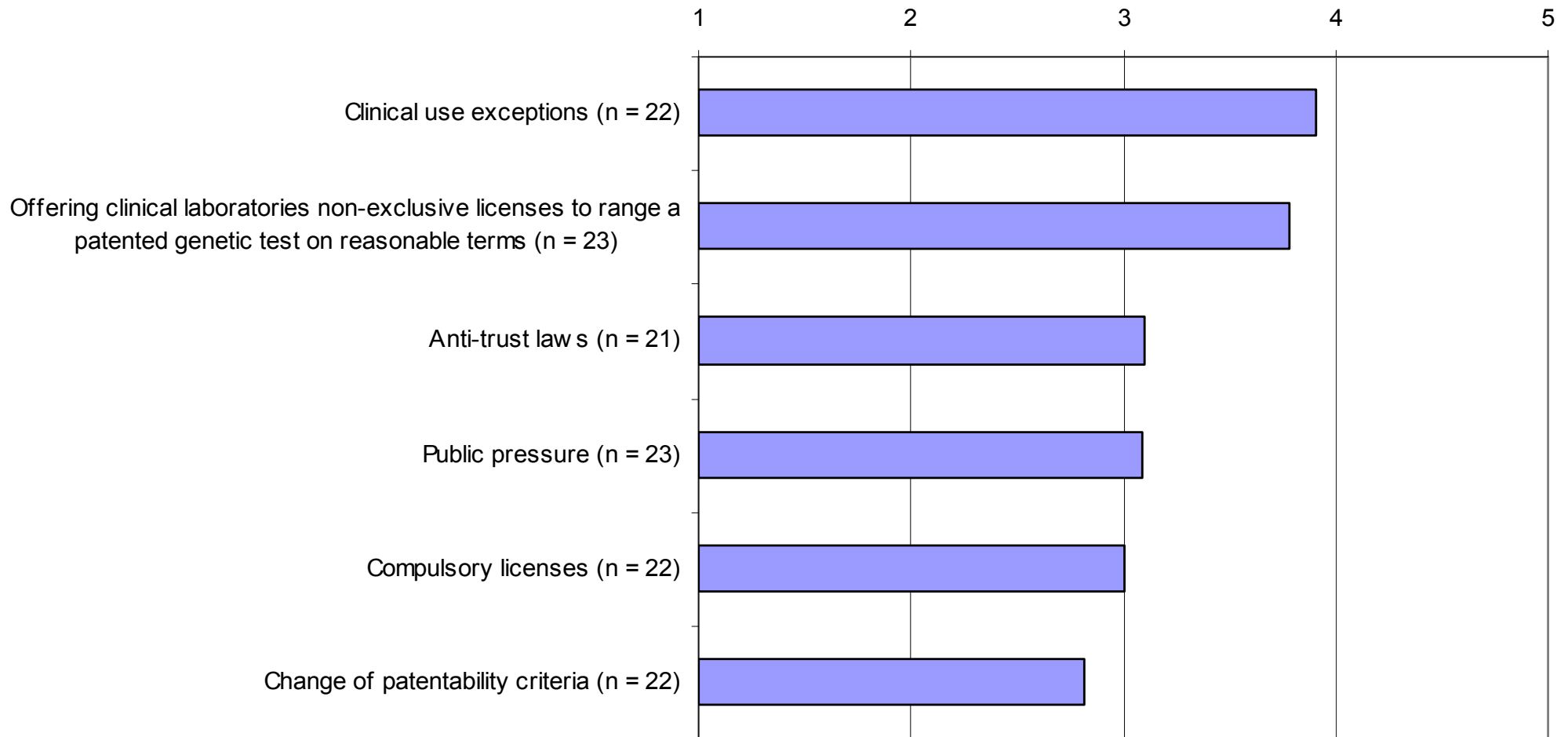
5. Main problems with patents on genetic tests



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

