Bern, 19 April 2005

Intellectual Property Rights, Innovation and Public Health

Meeting between the WHO Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH) and interested Federal Offices of the Swiss Government at the Swiss Federal Institute of Intellectual Property Einsteinstrasse 2, CH-3003 Bern
Bern, 19 April 2005

Some relevant aspects of the on-going revision of the Swiss Patent Law

Felix Addor
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Swiss Federal Institute of Intellectual Property
Principal topics

Protection of biotechnological inventions

Ratification of the 2000 Act Revising the European Patent Convention

Ratification of the London Agreement of the European Patent Convention

Compulsory license for the export of pharmaceutical products

Miscellaneous: parallel imports, counterfeiting, and piracy etc.

Swiss Federal Patent Court
Patent attorney

Swiss Federal Patent Court
Patent attorney
Protection (P) vs. Innovation (I)
Exclusions: Ordre Public and Morality

Art. 2(3) of the draft CH patent law:

- refers to the violation of human dignity and the disregard of the dignity of plants and animals
- includes an illustrative list of inventions contrary to ordre public (in force since 1 March 2005 / proposed amendments):
  - processes for cloning human beings
  - processes for producing hybrids or chimeras
  - processes for human parthenogenesis
  - germ line therapy
  - unmodified human embryonic stem cells
  - uses of human embryos (non-medical uses)
  - processes for genetic modification of animals likely to cause suffering
DNA Patents

CH Survey: Extent of Experience of Problems with DNA Patents (1=never, 5=very often)

Concrete Disclosure Functions

CH Survey: Extent of Experience of Problems with DNA Patents (1=never, 5=very often)

DNA Patents: Remedies

CH Survey: Remedies (named as many times as effectively to ...)

Scope of protection for genes

Art. 8c of the draft CH patent law intends to introduce a „function-limited“ protection:

- All processes to make the product are protected (even if unknown to the inventor and not disclosed in the application)
- Only the specific functions (uses) disclosed in the patent application are protected
- Patents for new uses or medical indications are still possible and independent of the product patent
Research/experimental use exemption

- Use of the invention for research purposes
  - every act is exempted that aims at elaborating new knowledge about the subject matter of the invention
  - **Clinical trials** in view of the submission for a market authorisation
- The invention must be the object and not the instrument of research
  - there is no free use of „research tools“
  - but the draft bill proposes a **legal license**
Genetic Testing

- Patents on genetic tests can lead to abusive monopoly positions. (n = 9/5/6)
- Patents increase costs of genetic testing. (n = 9/5/6)
- Tests were not developed due to the existence of patents. (n = 9/5/6)
- Patents have a negative impact on access to genetic testing. (n = 9/5/6)
- Patents increase the quality of genetic testing. (n = 9/5/6)
- Patent owners or licensees prevent laboratories from continuing testing services. (n = 9/5/6)
- Patents improve the information sharing between researchers. (n = 9/5/6)
- Our research staff is unaware of the legal implications of using patented research tools. (n = 9/5/6)
Remedies

Clinical use exceptions (n = 22)

Offering clinical laboratories non-exclusive licenses to range a patented genetic test on reasonable terms (n = 23)

Anti-trust laws (n = 21)

Public pressure (n = 23)

Compulsory licenses (n = 22)

Change of patentability criteria (n = 22)
Compulsory license for diagnostic testing

- **Bottleneck situations** are likely in case of diseases that are caused by a defect of a single gene or few genes.

- Abusive behaviour: e.g. BRCA1-gene (breast cancer)

- **Compulsory license in case of breach of antitrust law** (abuse of dominant position/agreement restricting competition)
Bern, 19 April 2005

The Discussion about IP and Patents at the WTO and National Implications

Mathias Schaeli
Head Legal Services International Trade Relations
Swiss Federal Institute of Intellectual Property
TRIPS Agreement and Public Health

WTO Declaration on TRIPS and Public Health
(‘Declaration’, Doha, 14 November 2001)

- Clarification of the relationship between the TRIPS Agreement and public health policies of WTO Members

- «Recognition» of key TRIPS flexibilities

- All WTO Members have the right to use, to the full, the provisions in the TRIPS Agreement which provide flexibility for this purpose!

⇒ TRIPS reconciles IP with public health policies
TRIPS Agreement and Public Health

Paragraph 6: The Gordian knot in the Doha Declaration:

How can WTO Members without or with insufficient manufacturing capacities in the pharmaceutical sector make effective use of compulsory licenses?
Para. 6 of the WTO Doha Declaration on TRIPS Agreement and Public Health

Position of Switzerland in the negotiating process

• Pinpointed approach => effective solution for the real problem: ACCESS TO DRUGS FOR THE POOR - without undermining the TRIPS patent protection in general

• Importance of IP protection for R&D of new pharmaceuticals

• Solution must not be abused for the sake of commercial/competitive interests of generics manufacturers to the detriment of R&D of innovative pharmaceuticals!

• «Yes, drugs for the poor - but patents as well»
  (Mike Moore, International Herald Tribune, 22.02.2001)
Follow-up to WTO’s Decision of 30 August 2003

Tasks still to be accomplished:

1. Implementation of the para. 6 solution in the TRIPS Agreement:
   Deadline of March 2005 missed => ongoing consultations in the TRIPS Council

2. Implementation of the WTO Para. 6 Decision by Members at the national level
Follow-up to WTO’s Decision of 30 August 2003

Swiss Government proposes to implement WTO’s Para. 6 Decision as part of the ongoing revision of its Patent Law:

- Coherent step following its position in WTO discussion
- Switzerland: Opted out as a beneficiary country!
- National implementation to put Swiss manufacturing capacity in the pharmaceutical factor at the disposal of developing countries in a Para. 6 situation
WTO Para. 6 Decision of 30 August 2003
Switzerland’s implementation at the national level

Results of the **Swiss internal consultation procedure**

- Proposal to implement WTO Decision at the national level is non-controversial
- Pharmaceutical industry emphasizes need to ensure safeguards against diversion of such pharmaceuticals
- NGOs urge not to limit scope of diseases; emphasize need for simple administrative procedures and moderate remuneration to patent holder to keep prices low
WTO Para. 6 Decision of 30 August 2003
Switzerland‘s implementation at the national level

Article 40c of draft proposal for Patent Law Revision

- **Scope of diseases** = WTO Decision of 30 August 2003, i.e. public health problems such as those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics
- **Scope of products** = All pharmaceuticals, active substances, diagnostic kits AND vaccines
- **Eligible beneficiary countries** = Any country without or insufficient manufacturing capacity in the pharmaceutical sector in a para. 6 Decision situation, including non-WTO Members! (Exclusion of WTO Members which declared opt out)
- **Safeguards against diversion** = Licensee must ensure product differentiation from original product
- Federal Council will specify more detailed conditions for the grant of such licences in the Patent Ordinance
WTO Para. 6 Decision of 30 August 2003
Switzerland‘s implementation at the national level

Timetable / state of play of revision of Swiss Patent Law:

- **October 31, 2004:**
  End of 2nd round of national consultation (start July 1, 2004)

- **March 11, 2005:**
  - Report of results of national consultation process published
  - Mandate by Federal Council to work out proposal for revised Patent Law

- **Before end of 2005:**
  Draft revised Patent Law scheduled to be presented to Parliament

- **?**
  Entry into force of revised Patent Law (including revised Patent Ordinance)
WTO Para. 6 Decision of 30 August 2003
Switzerland’s implementation at the national level

Full text of the draft amendment proposal of the Swiss Patent Law at:


Documents on the Swiss internal consultation procedure at:

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

Abraham Lincoln