

Disclosure Requirement and ABS-Regulations in Switzerland

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Based on Swiss Biotech Report 2014



Time often more than 10 years

→ Legal certainty to support innovation !

- Federal Act on Patents for Inventions
- Ordinance on Patents for Inventions
- In force since 2008



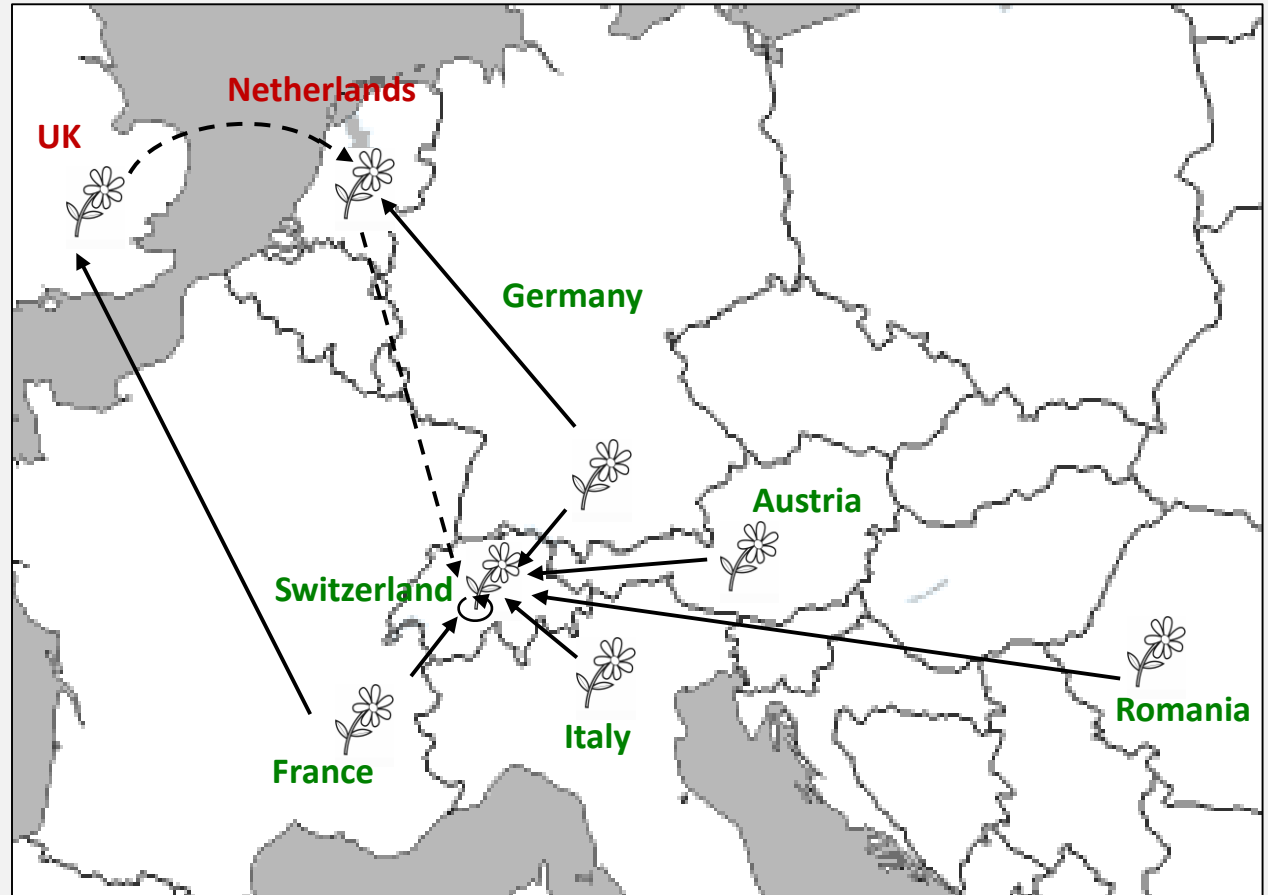
Objectives:

- Enhance transparency about the genetic resource (GR) and/or associated traditional knowledge (ATK), on which an invention is directly based on
- Support compliance with access and benefit-sharing (ABS)

1. Content: Source of GR and/or ATK
2. Trigger: Inventions directly based on GR and/or ATK
3. Sanctions: Pre-grant and post-grant sanctions
 - but no revocation, as it would run counter to the objectives of benefit-sharing and legal certainty !



«Edelweiss»
Leontopodium alpinum



- Primary source → e.g. France, the country of origin that supplied the GR
- If not known, secondary source → e.g. Botanic Garden the Netherlands

Trigger – «Directly Based On»

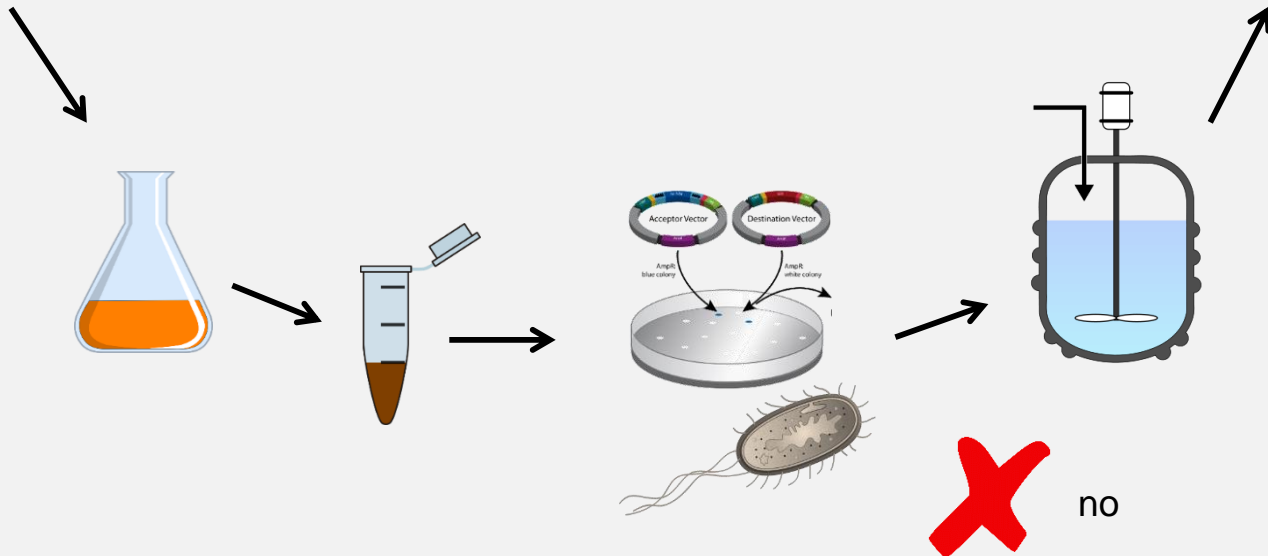
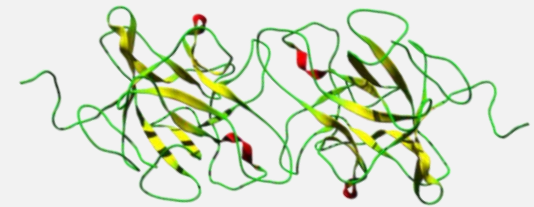
Miracle fruit
Origin tropical West Africa



yes

Disclosure

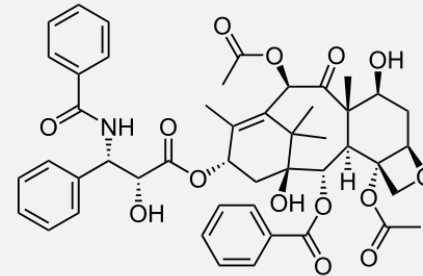
Miraculin, a glycoprotein
that turns sour to sweet



Disclosure



Pacific yew
Taxus brevifolia



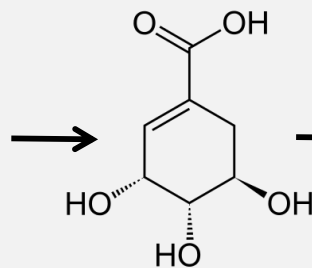
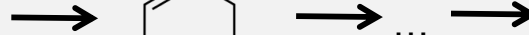
Paclitaxel or *Taxol*[®]



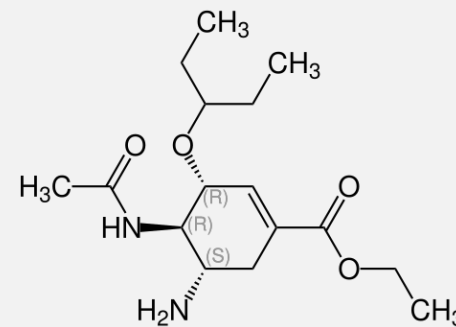
yes



Chinese Star Anise
Illicium verum



Shikimic acid



Oseltamivir, the active compound in *Tamiflu*[®]



no

- 2014: Ratification and amendment of Federal Act on Protection of Nature and Cultural Heritage
- 2016: Nagoya - Ordinance on ABS

Content:

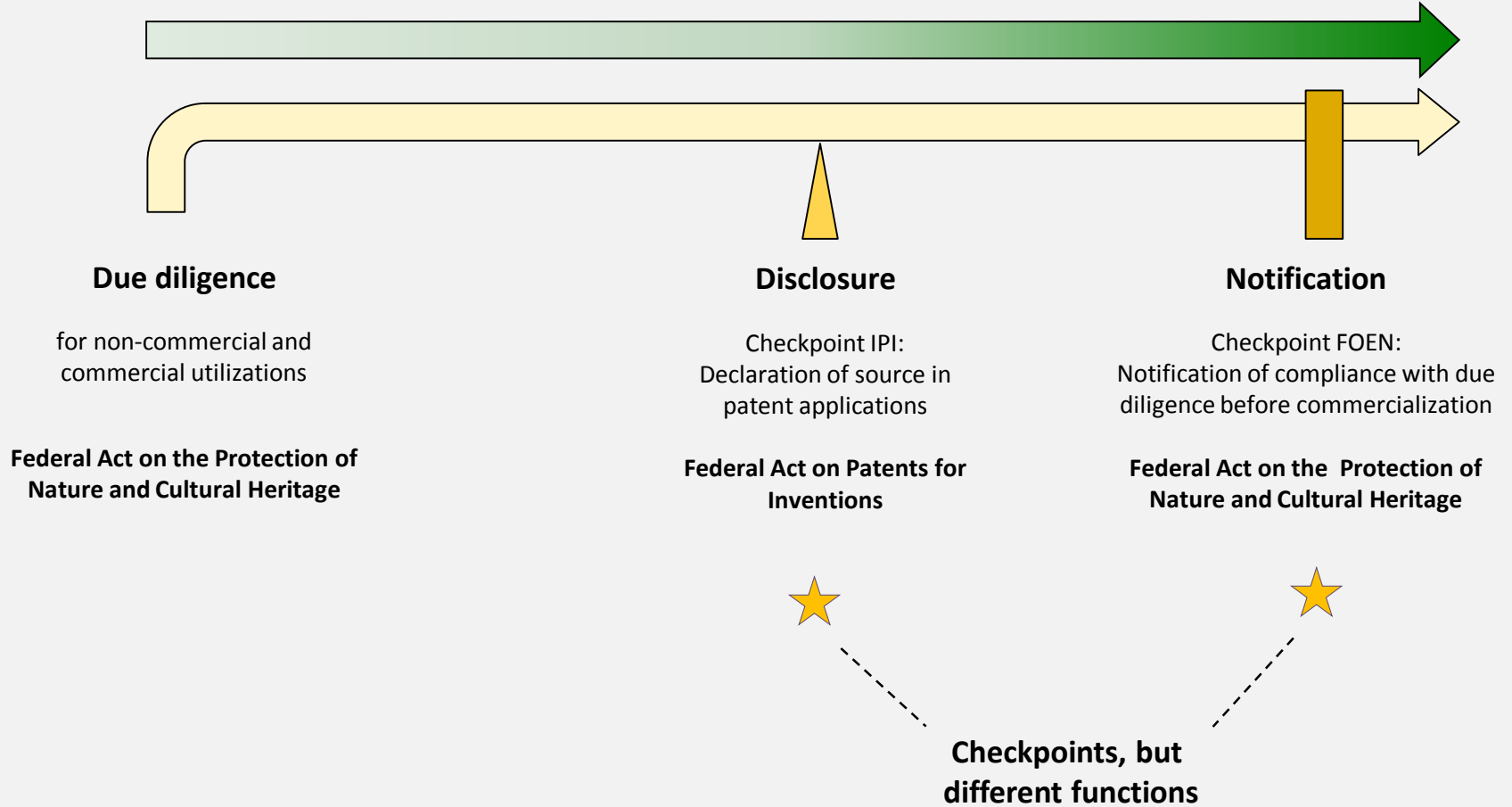
- ABS user compliance measures for GR and ATK of other Parties
- Access provisions for GR in Switzerland



Convention on
Biological Diversity

- Due diligence → approach similar as in the EU
 - Information to provide evidence that national ABS-regulations have been respected
- Notification to the Federal Office for the Environment that due diligence was applied at the time of commercialization
- Sanctions for non-compliance → fines and administrative measures
- Applicable, if GR was accessed after 12 October 2014 in another Party to the Nagoya Protocol that has access regulations in place

Value chain of the utilization of GR and TK associated with GR



- 2005: Ratification of the International Treaty on Plant Genetic Resources for Food and Agriculture (Plant Treaty)
- 2014: Ammendment of the Federal Act on Agriculture:
 - Delegation Norms for GR for food and agriculture
- 2016: Ordinance on Plant Genetic Resources for Food and Agriculture:
 - ABS Regulations for plant GR in the national gene bank
 - All plant GR of the national gene bank are included in the MLS of the Treaty,
→ not covered by the ABS measures under Nagoya



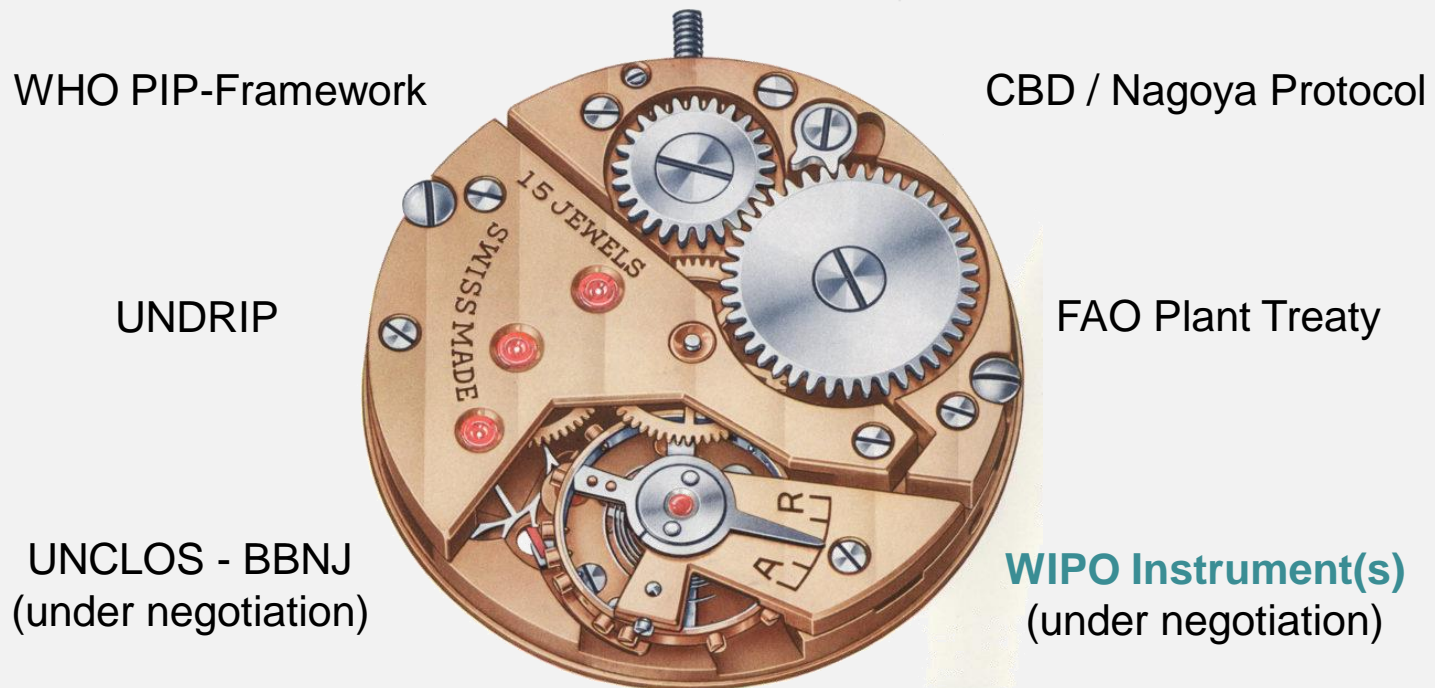
- Disclosure Requirement in Patent Act
 - Transparency measure for GR and ATK in patent applications
 - Clear and practical trigger and content
 - Appropriate sanctions (→ no revocation)
- ABS-Regulations
 - Based on Nagoya Protocol and Plant Treaty
 - Implemented outside of the Patent System in environmental and agricultural laws

→ **Mutual supportiveness !**



- Support innovation on GR and benefit-sharing
- Not a one-size-fits-all approach - various instruments are needed

International Regime



- Summary of the disclosure requirement in the Swiss Patent Act: [WIPO/GRTKF/IC/16/INF/14](#)
- Further explanations, including views on the role of WIPO in the context of disclosure requirements: [WIPO/GRTKF/IC/31/8](#)



Thank You for Your Attention

