VISCHER

How to Protect, Develop and bring onto the Market your Drug Innovation

Swiss Russian Forum

September 10/11, 2012

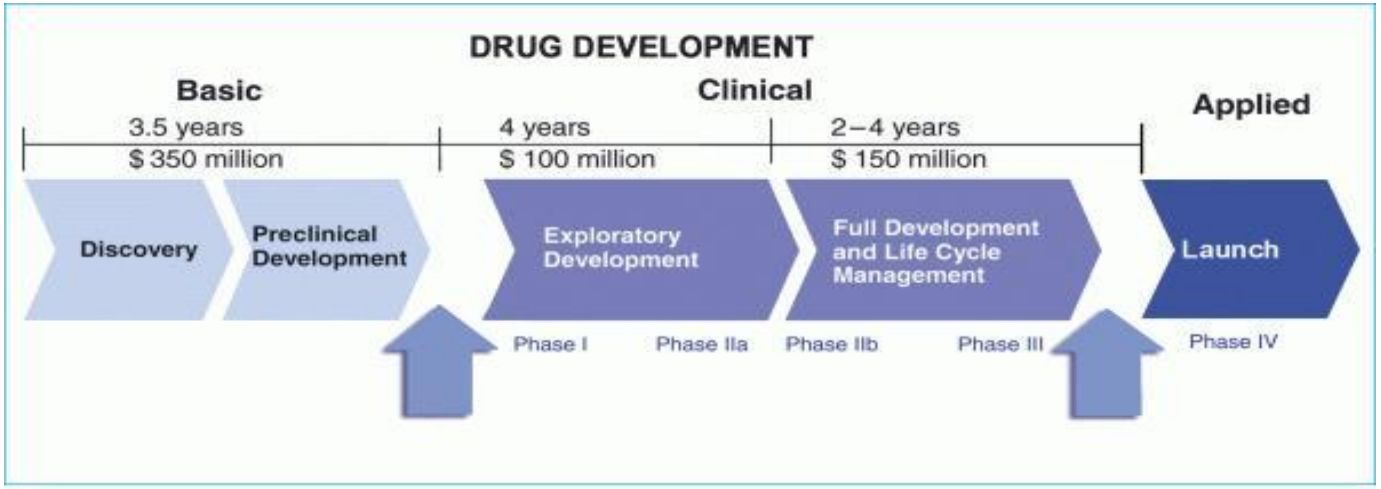
Basel

Stefan Kohler

Russia joined WTO

- August 22, 2012: Russia joined the World Trade Organization (WTO)
  - Russia's trading laws need to be brought into compliance with the international standards set under the WTO
  - WTO includes: Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS)
    - Minimum standards for the protection of intellectual property
    - Specific enforcement procedures, remedies, and dispute resolution procedures
- Russia expected to align its IP system with TRIPs standards – as already implemented in Europe

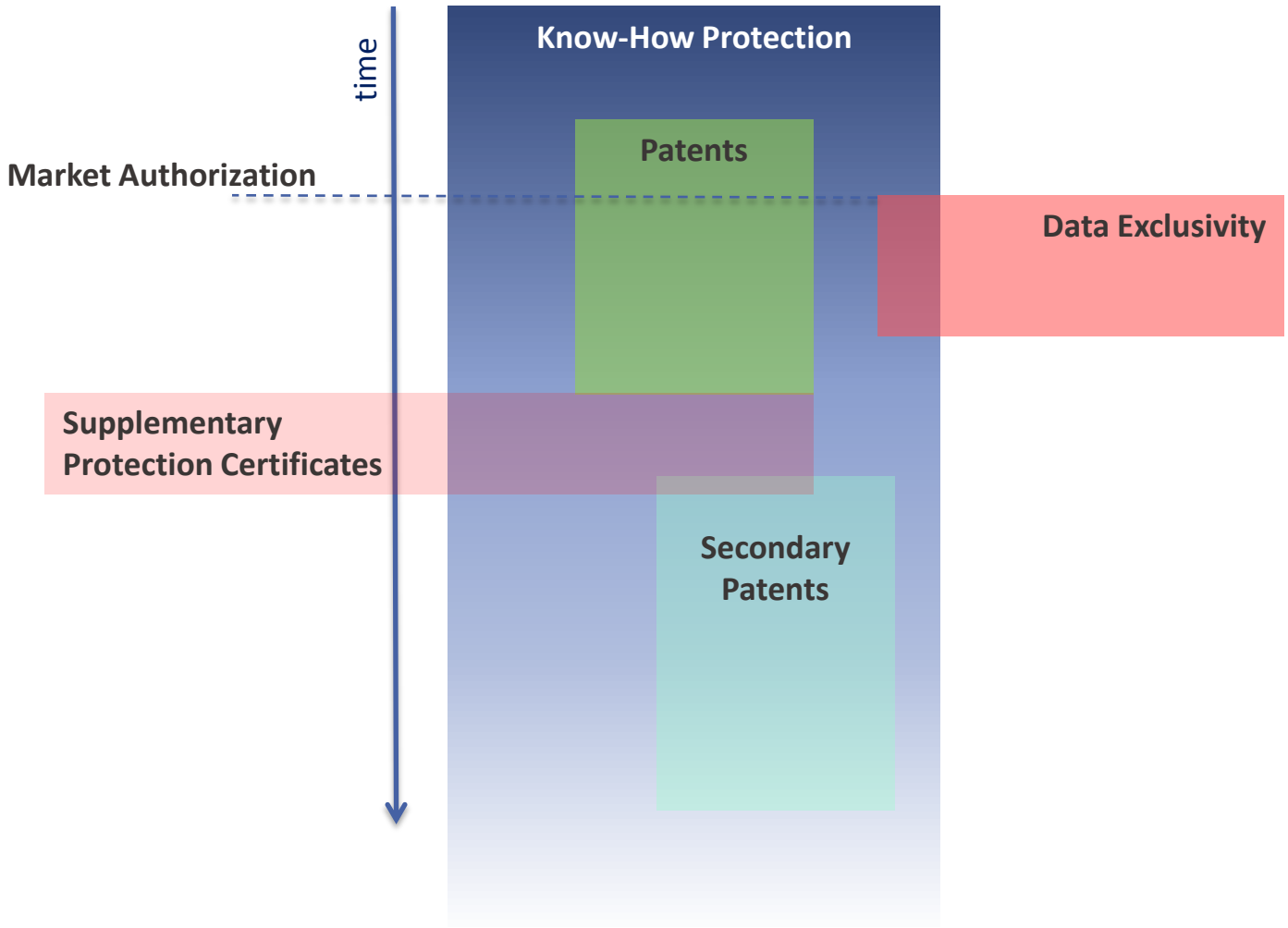
Pharmaceutical Industry Depending on IP



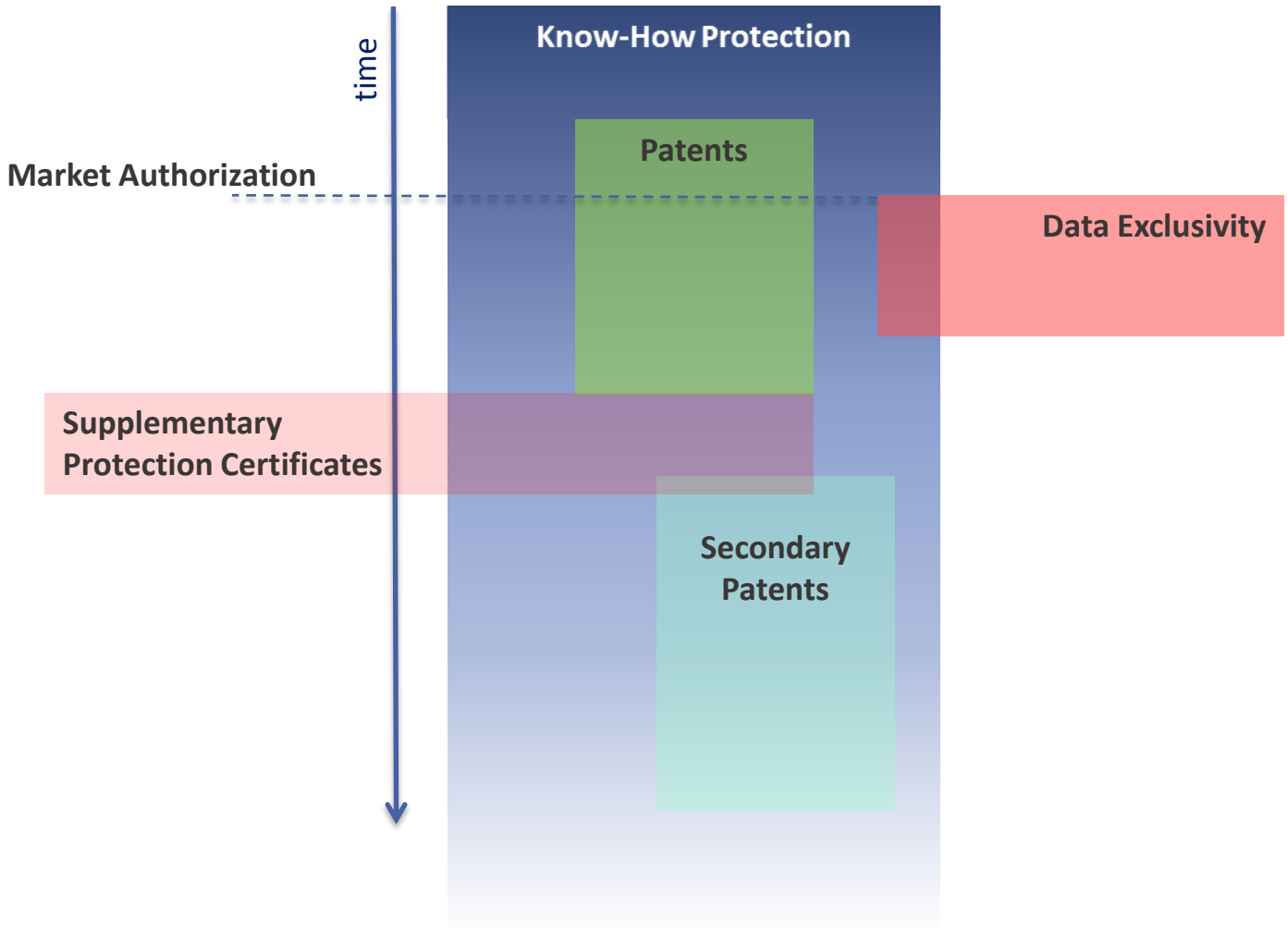
Mattisson DR, Mattison Faye AC Blickpunkt der Mann 2008; 6 (1): 21-25 ©

- Large investments in research and development
- Long and expensive regulatory processes required to take new pharmaceutical products to market
  - ➢ Relying on the IP system to recover R&D investments is crucial for pharmaceutical companies

Product Exclusivity Lifecycle



Product Exclusivity Lifecycle



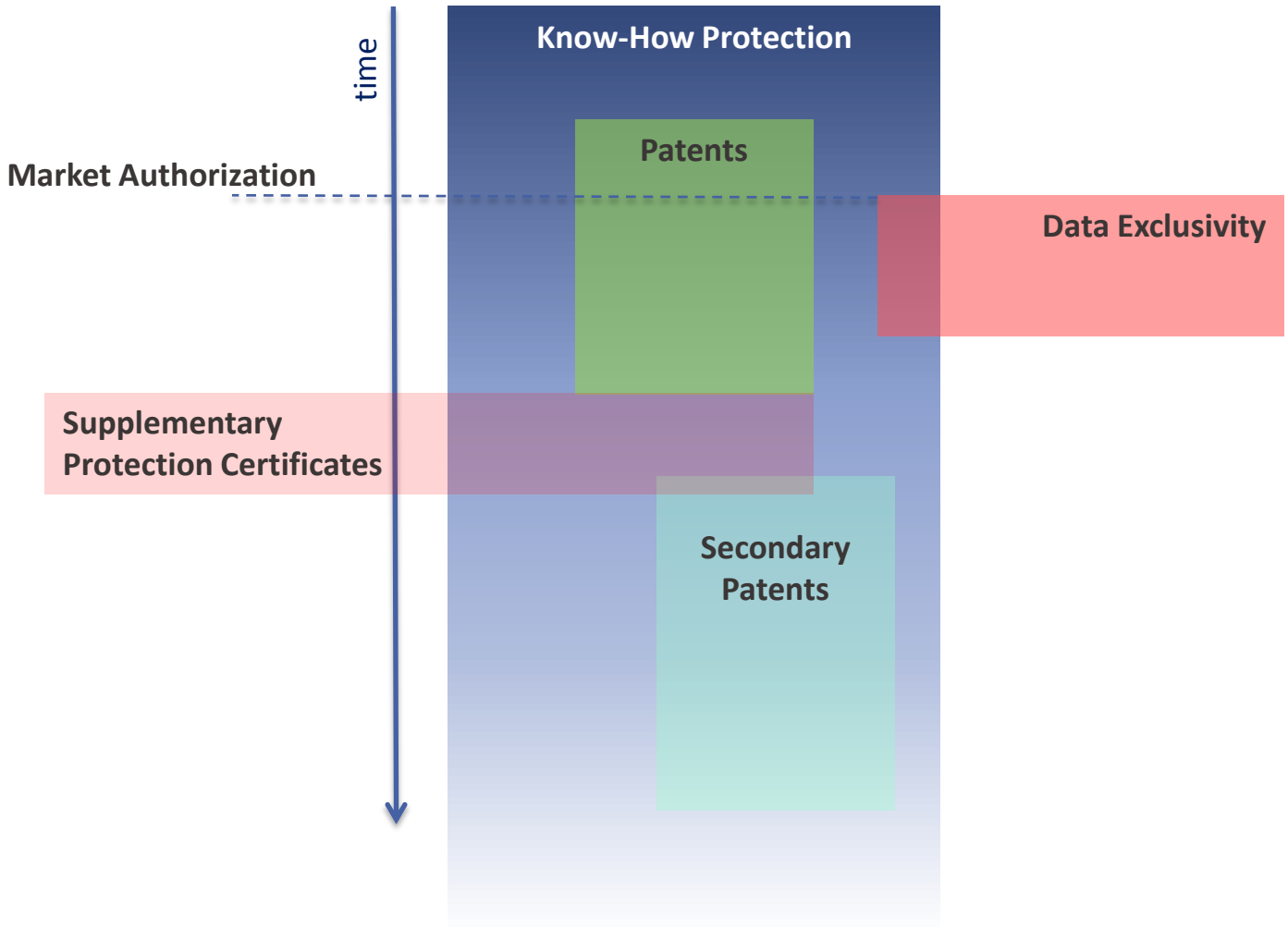
Protection of Know-how

- **Know-how** is proprietary information relating to materials, procedures or methods, together with accumulated skills and experience

- **Know-how** is often co-existing with IP rights
- **Know-how** and IP rights complement each other
- **Know-how** is exposed to the «freedom-to-use» principle

- **Know-how** needs to be secured and kept confidential
  - Assignment of research and development results to employer/company
  - Confidentiality obligations for employees, consultants etc.
  - Nondisclosure agreements vis-à-vis business partners
  - Restricting distribution

Product Exclusivity Lifecycle



Legal Environment for Patents in Europe

- International level
  - International Treaties (e.g., WTO/TRIPS, PCT etc.)

- Regional level
  - European Patent Convention
  - Directive 98/44/EC on the legal protection of biotechnological inventions
  - Regulation No 1768/92 concerning supplementary protection certificates for medicinal products
  - [more]

- National level
  - National Patent Acts (e.g., Swiss Patent Act)

Patent Protection

- An invention is **patentable** if it is
  - novel (not «prior art»)
  - inventive (not obvious)
  - useful (commercially applicable)

- A **patent** is
  - an exclusive right to commercially use an invention
  - granted by a state to an inventor or assignee
  - for a limited period of time
  - in exchange for a public disclosure of such invention

Exemption for Medical Treatment Methods

- Exempted from patentability are
  - ➢ methods for medical treatment of human or animal body
    - therapy
    - surgery
    - diagnostic methods

- Exemption does not apply to products (e.g., substances or compositions) for use in medical treatment methods

Ethical or Moral Reservations

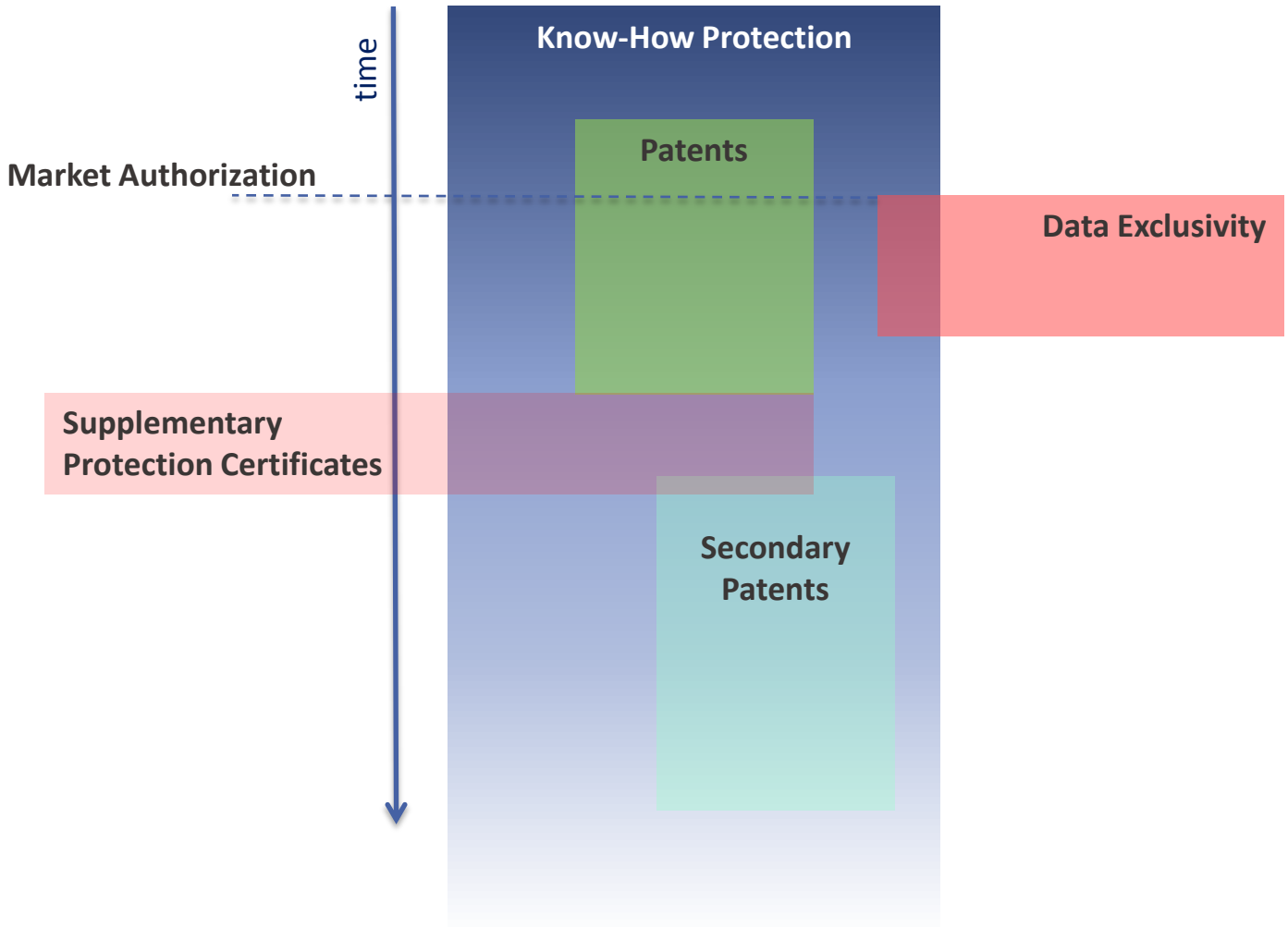
- Exempted from patentability are inventions concerning
  - processes for cloning human beings
  - modification of the germ line genetic identity of human beings
  - use of human embryos for industrial or commercial purposes
  - modifying the genetic identity of animals likely to cause them suffering
  - human body and its elements
  - nucleotide and amino acid sequences without specified application
  - plant and animal varieties
- Limited validity and enforceability in case of ethical or moral reservations

Second and Further Medical Use

- An already known substance or composition not yet used in a medical treatment is patentable for use in a medical treatment («first medical use»)
- An already known substance or composition used in a medical treatment is patentable for the use in a new therapeutic application («further medial use»)

  - scope of protection limited to a specific «medical use»

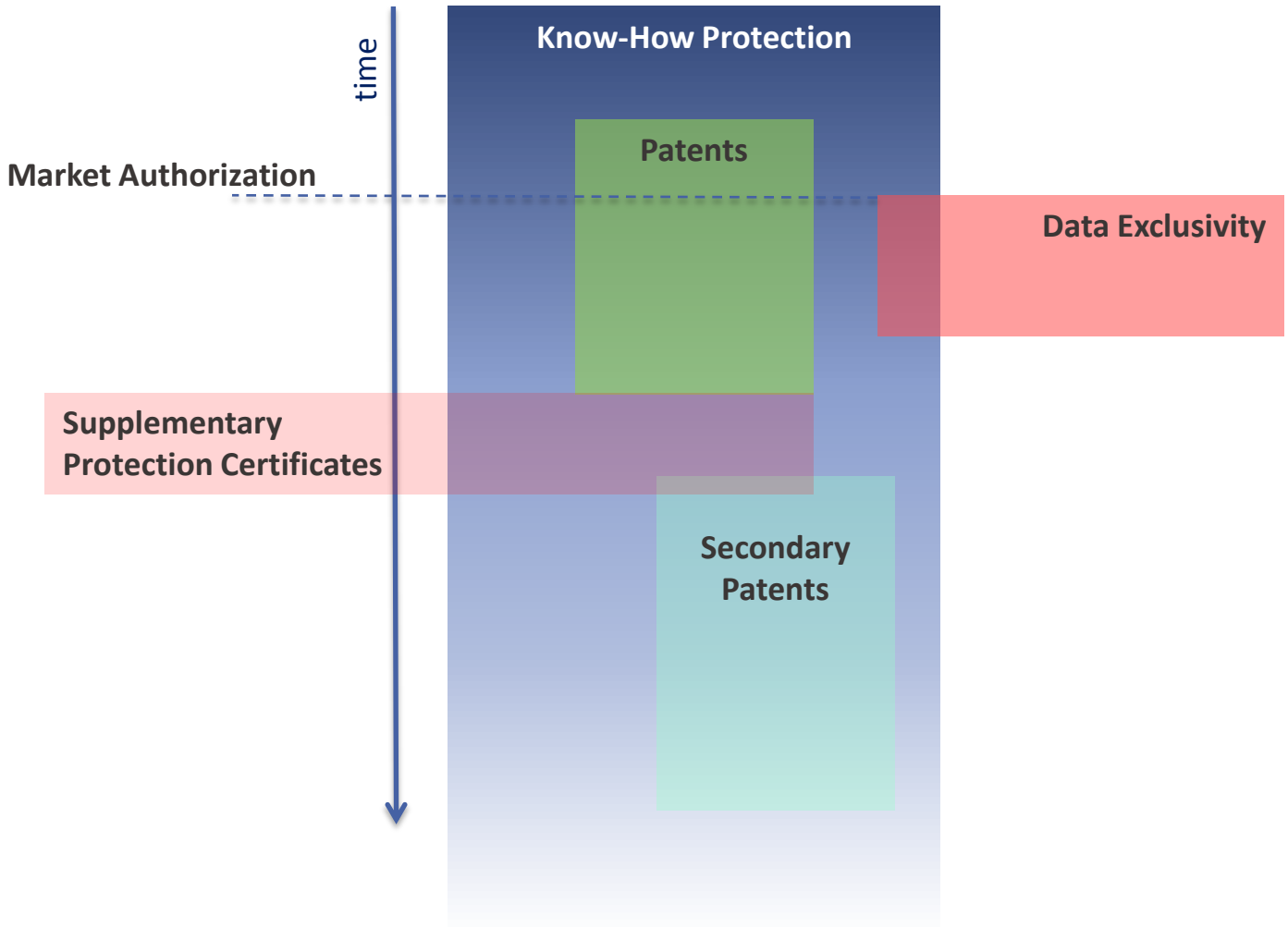
Product Exclusivity Lifecycle



Supplementary Protection Certificate (SPC)

- Article 33 WTO/TRIPs: «The term of protection available [for patents] shall not end before the expiration of a period of twenty years counted from the filing date»
- SPCs compensate the long duration drug development to market
- An SPC comes into force only after the corresponding patent expires
- SPC normally has a maximum lifetime of 5 years (extended to 5.5 years for paediatric medicines)
- The total combined duration of market exclusivity of a general patent and SPC cannot normally exceed 15 years
- SPCs do not extend patent protection but provide protection limited to a specific medical product approved for marketing (IP right «sui generis»)

Product Exclusivity Lifecycle

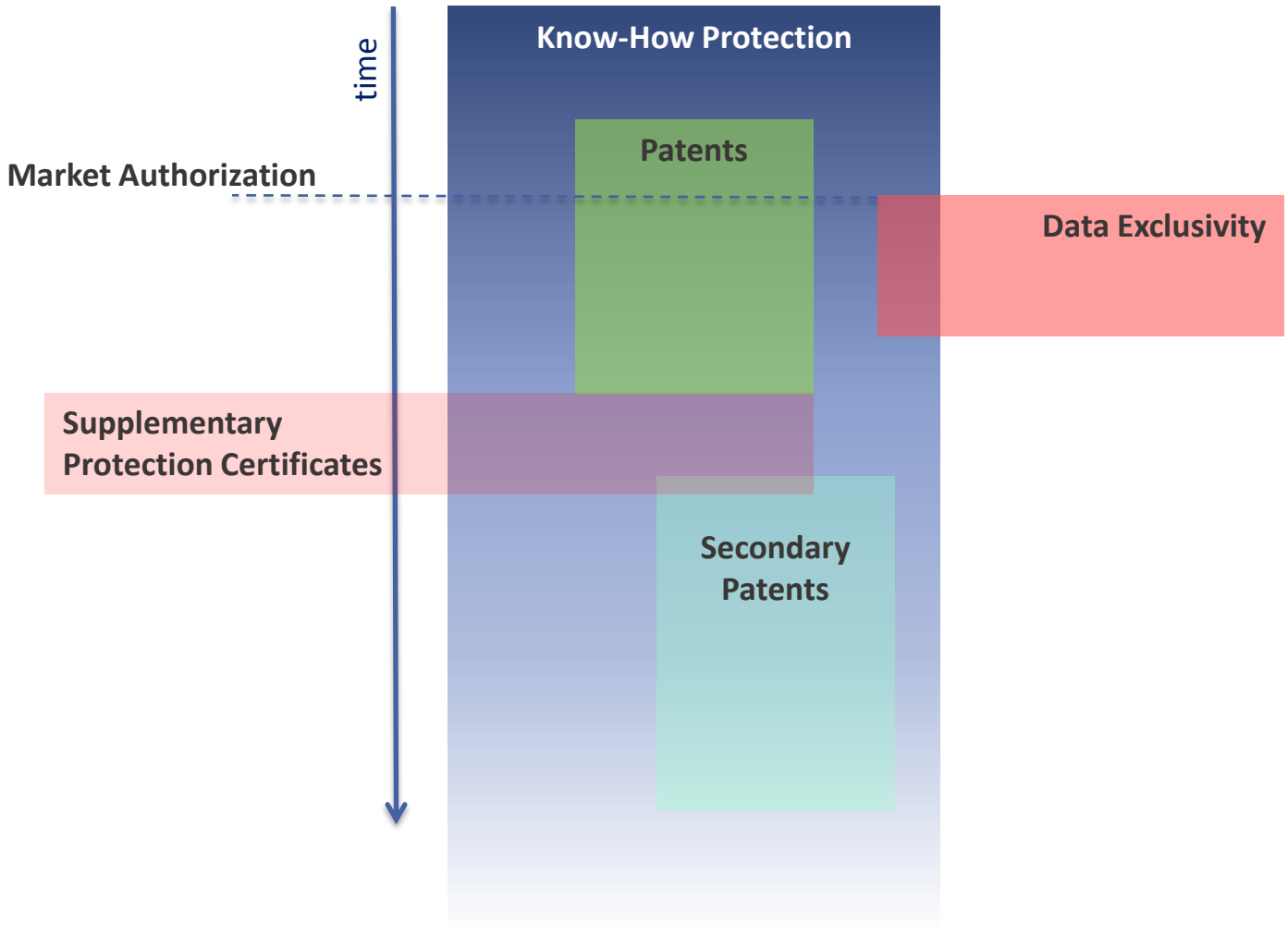


«Evergreening» by «Secondary Patents»

- «Secondary Patents» are patents for modifications of existing patented products
- «Secondary Patents» are necessarily narrower in scope than the earlier patent
- Following expiry of the earlier patent, «Secondary Patents» cannot preclude a generic competitor from selling products defined in the earlier patents and which are not covered by the «Secondary Patents»

  - «Secondary Patents» result in an economic success only if they concern medically valuable improvements

Product Exclusivity Lifecycle



Test Data Exclusivity

- **Test data exclusivity** protects clinical test data submitted to a regulatory agency from generic drug manufacturers to rely on this data in their own applications.

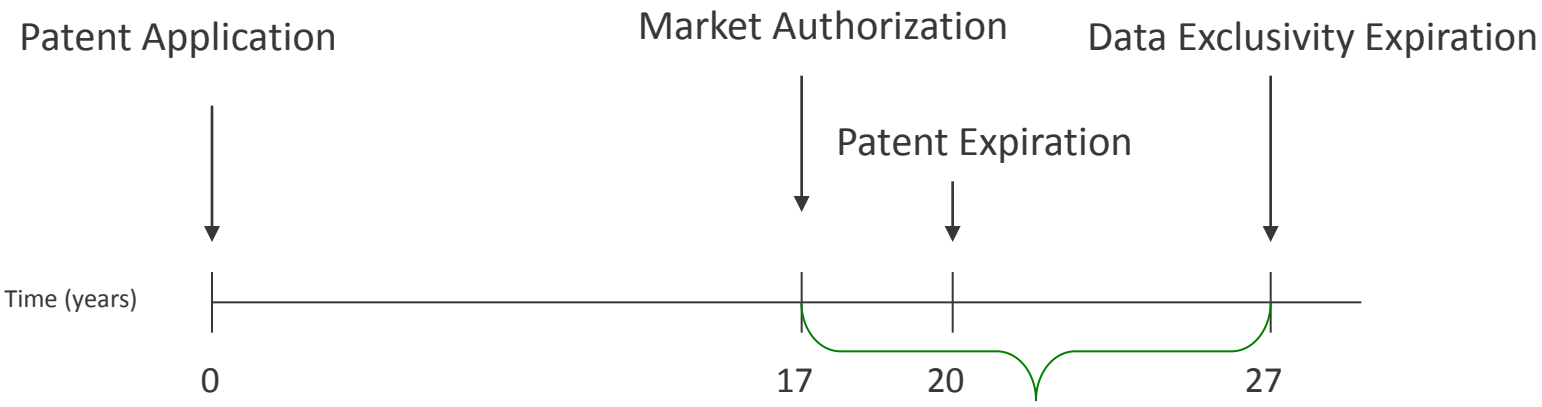
- Legal Basis: Article 39.3 WTO/TRIPs

Duration of Test Data Exclusivity (Switzerland)

- New Chemical Entities (NCE)
  - 10 years *ex officio*

- New indication, new administration form, new administration pathway, new dosage form
  - 3 years *ex officio*; upon application/request max. 5 years

Effect of Test Data Exclusivity (example)



No access to clinical data for generic competitors during 10 years

Conclusions

- No business in the pharmaceutical industry without effective IP protection
  - Systematically keep innovative ideas confident
  - Plan and implement your IP strategy by using the opportunities offered by the various IPRs and "sui generis" IP
  - Exploit your IP rights (own product sales, partnering, license arrangements, transfer agreements, etc.)
  - Administer, manage, enforce and defense your IP rights to get best possible long-term prospects and exclusivity

VISCHER

Thank you!

Stefan Kohler
Dr. iur. et dipl. sc. nat. ETH
Tel +41 58 211 34 19

Zürich
Schützengasse 1
Postfach 1230
CH-8021 Zürich
Tel +41 58 211 34 00
Fax +41 58 211 34 10

Basel
Aeschenvorstadt 4
Postfach 526
CH-4010 Basel
Tel +41 58 211 33 00
Fax +41 58 211 33 10