Supplerende beskyttelsessertifikater (SPC)

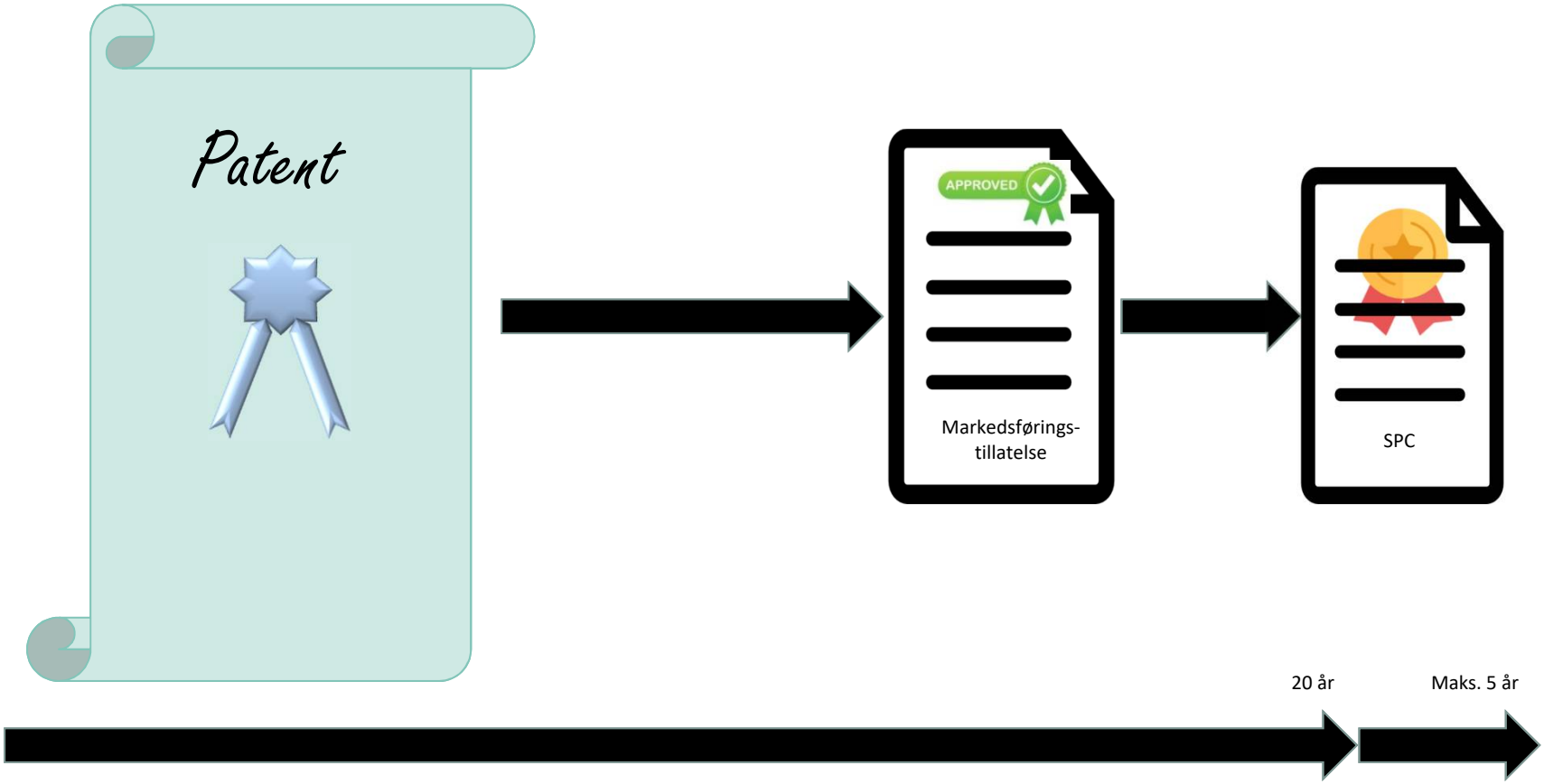
Skjæringspunktet mellom patentrett og EØS-rett

NIR – miniseminar patentrett

3.12.2019 | Knut Sverre Skurdal Andresen

SCHJØDT

HVA ER ET SUPPLERENDE BESKYTTELSESSERTIFIKAT?



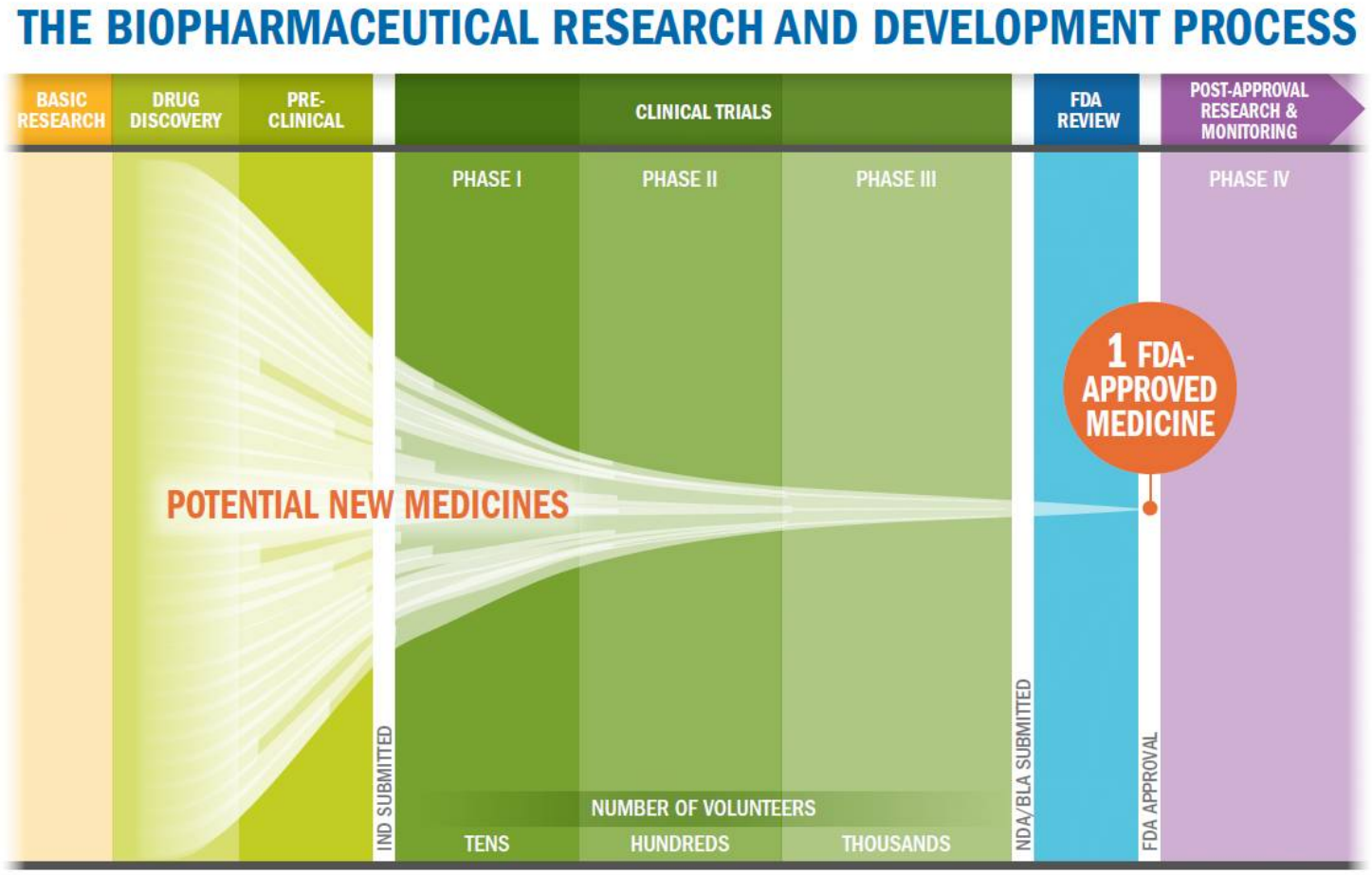
OPPLEGG

1. Bakgrunnen for SPC-regelverket
2. Utfordringer ved tolkningen av SPC-forordningen
3. Vilkårene for å få meddelt et SPC
4. Veien videre?

1. BAKGRUNNEN FOR SPC-REGELVERKET

- Forordning 1768/92/EEC concerning the creation of a supplementary protection certificate for medicinal products
  - Nå forordning 469/2009/EC
- Forordning 1610/96/EC concerning the creation of a supplementary protection certificate for plant protection products
- Gjennomført i norsk rett ved nytt kapitel 9a i patentloven
  - «EØS-avtalen vedlegg XVII punkt 6 (europaparlaments- og rådsforordning (EF) nr. 469/2009 om det supplerende beskyttelsessertifikatet for legemidler) gjelder som lov» (§ 62 a) – i kraft 1. juli 1994
  - «EØS-avtalen vedlegg XVII punkt 6 a (Europaparlamentets og Rådets forordning (EF) 1610/96 om innføring av et supplerende beskyttelsessertifikat for plantefarmasøytiske produkter) gjelder som lov» (§ 62 b) – i kraft 2. januar 1998

1. BAKGRUNNEN FOR SPC-REGELVERKET



Key: IND: Investigational New Drug Application, NDA: New Drug Application, BLA: Biologics License Application

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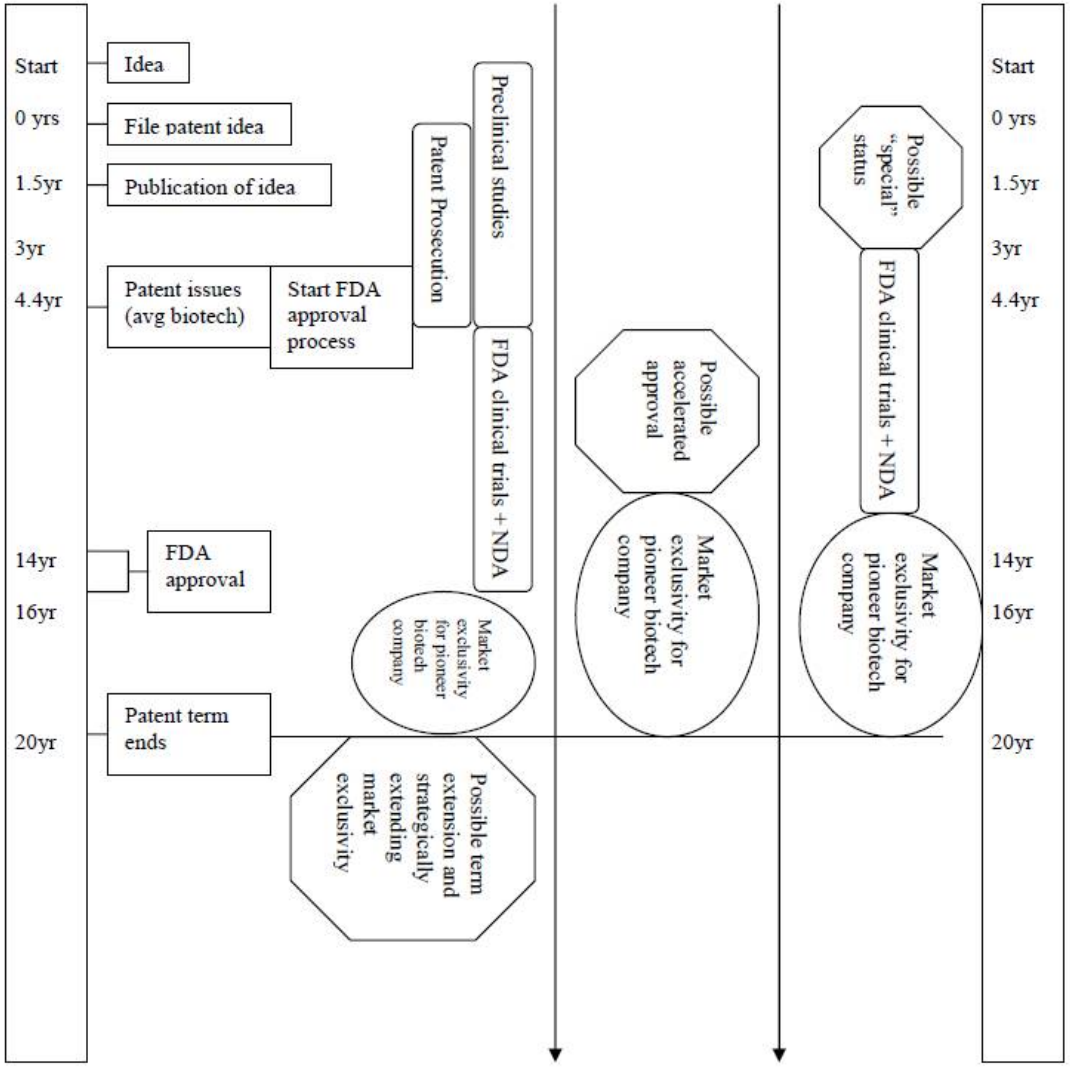


1. BAKGRUNNEN FOR SPC-REGELVERKET

- SPC-forordningens fortale
  - (2) Pharmaceutical research plays a decisive role in the continuing **improvement in public health**.
  - (3) Medicinal products, especially those that are the result of long, costly research will not continue to be developed in the Community and in Europe unless they are covered **by favourable rules that provide for sufficient protection to encourage such research**.
  - (4) At the moment, the **period that elapses** between the filing of an application for a patent for a new medicinal product and authorisation to place the medicinal product on the market makes the period of effective protection under the patent **insufficient** to cover the investment put into the research.

1. BAKGRUNNEN FOR SPC-REGELVERKET

- SPC-forordningens fortale
  - (10) **All the interests at stake**, including those of public health, in a sector as complex and sensitive as the pharmaceutical sector should nevertheless be taken into account. For this purpose, the certificate cannot be granted for a period exceeding **five years**. The protection granted should furthermore be strictly confined to the product which obtained authorisation to be placed on the market as a medicinal product.

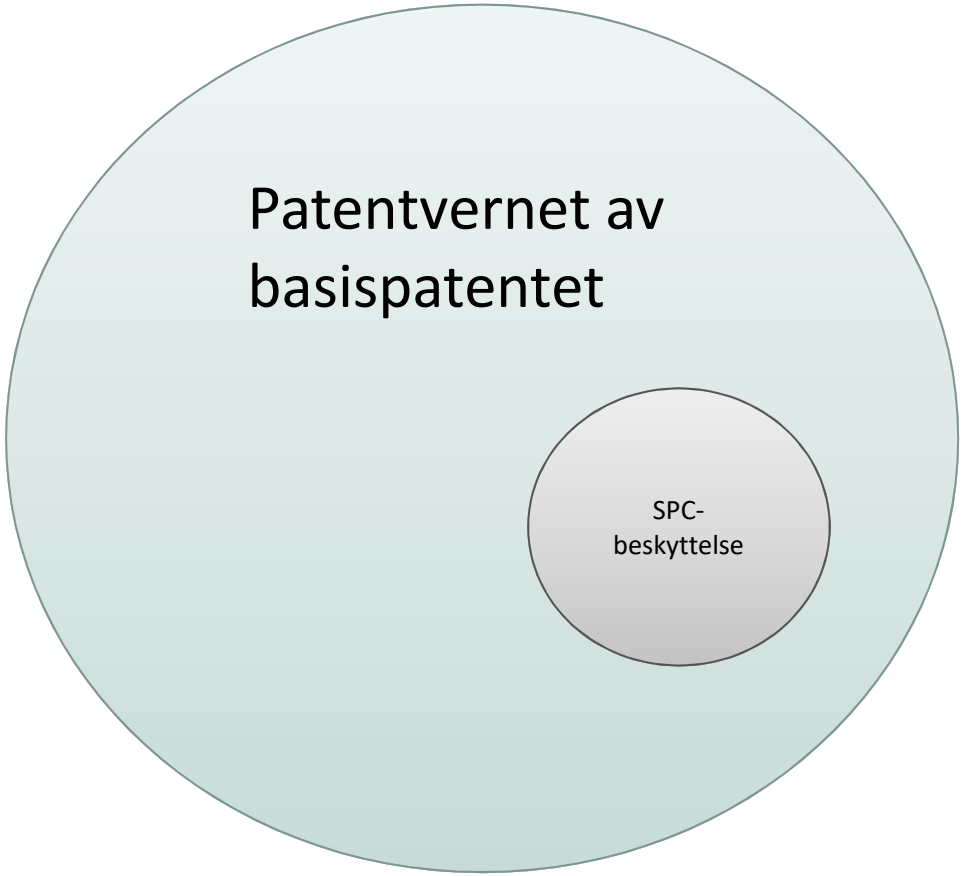
1. BAKGRUNNEN FOR SPC-REGELVERKET

- GA Hogan i opinion 11. september 2019 (C-650/17 og C-114/18 *Royal Pharma* og *Sandoz/Hexal*)
  - "A supplementary protection certificate ('SPC') is designed to re-establish a **sufficient period of effective protection** of the basic patent by permitting the holder to enjoy an additional period of exclusivity on the expiry of that patent, which is intended **to compensate, at least in part, for the delay to the commercial exploitation** of his or her invention by reason of the **time which has elapsed between the date on which the application for the patent was filed and the date on which the first marketing authorisation ('MA')** in the European Union was granted." (jf. C-493/12 avsnitt 41 *Eli Lilly*)

1. BAKGRUNNEN FOR SPC-REGELVERKET

- SPC-forodningen art. 5
  - "[…] **the certificate** shall confer the same rights as conferred by **the basic patent** and shall be subject to the same limitations and the same obligations."

2. UTFORDRINGER VED TOLKNINGEN AV SPC-FORORDNINGEN



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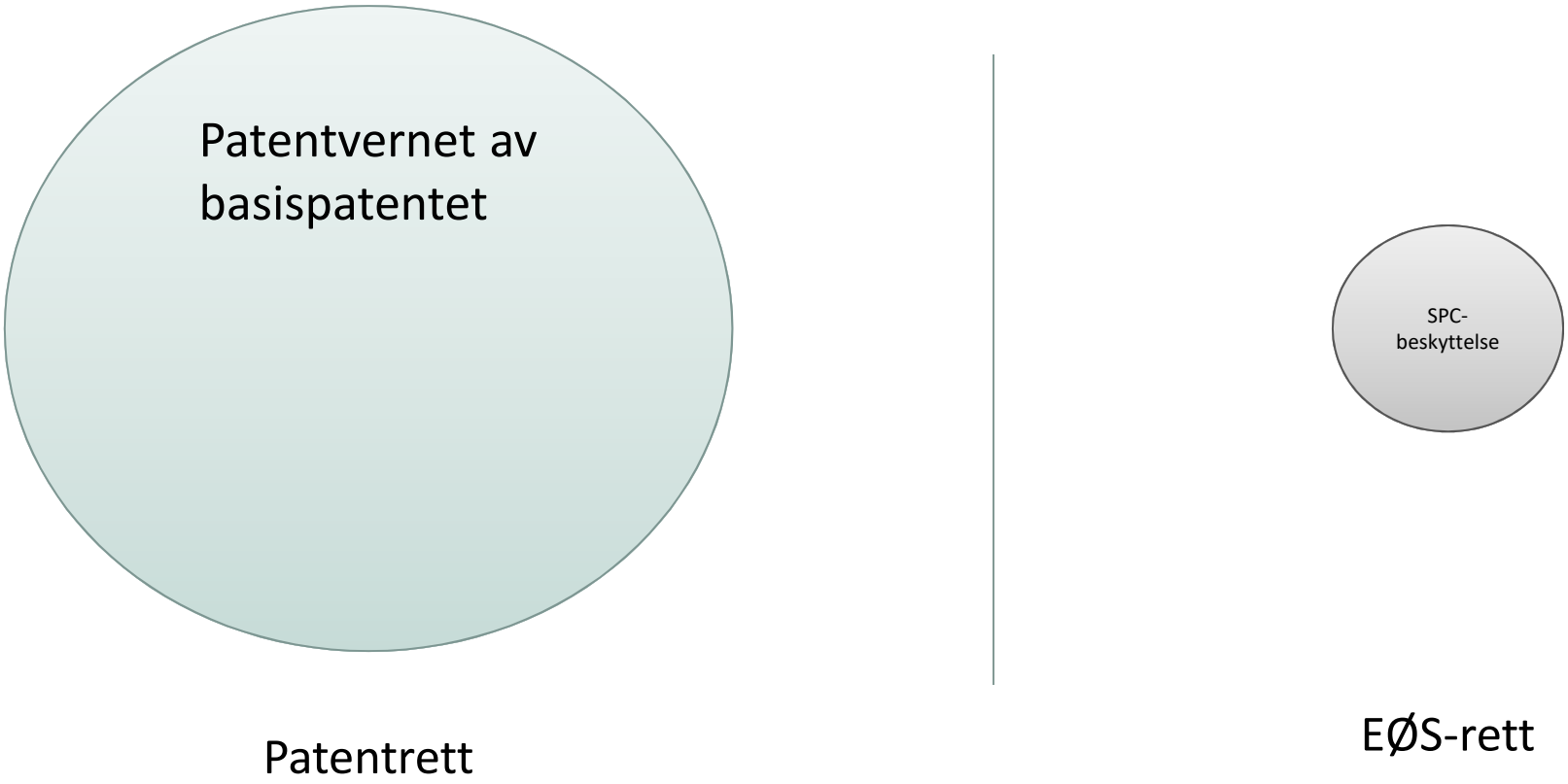

3. VILKÅRENE FOR Å FÅ MEDDELT ET SPC

- SPC-forordningen art. 3

"A certificate shall be granted if, in the Member State in which the application referred to in Article 7 is submitted and at the date of that application:

(a) the product is protected by a basic patent in force;

(b) a valid authorisation to place the product on the market as a medicinal product has been granted in accordance with Directive 2001/83/EC or Directive 2001/82/EC, as appropriate;

(c) the product has not already been the subject of a certificate;

(d) the authorisation referred to in point (b) is the first authorisation to place the product on the market as a medicinal product."

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3. VILKÅRENE FOR Å FÅ MEDDELT ET SPC

- Art. 3 (a) the product is protected by a basic patent in force;
  - "product" means the active ingredient or combination of active ingredients of a medicinal product, jf. art. 1 (b)
  - "patent in force" ("at the date of that application", jf. første setning i artikkelen)
  - "protected by" (?)
    - infringement test;
    - an Art. 123(2) EPC standard-disclosure test;
    - core inventive advance test

3. VILKÅRENE FOR Å FÅ MEDDELT ET SPC

- Art. 3 (a) the product is protected by a basic patent in force;
  - C-121/17 *Teva* (storkammeravgjørelse 25. juli 2018)
    - "a product cannot be considered to be protected by a basic patent in force within the meaning of Article 3(a) of Regulation No 469/2009 unless the product which is the subject of the SPC is **either expressly mentioned in the claims** of that patent **or** those claims relate to that product **necessarily and specifically**."

3. VILKÅRENE FOR Å FÅ MEDDELT ET SPC

- Art. 3 (a) the product is protected by a basic patent in force;
  - C-121/17 *Teva* (storkammeravgjørelse 25. juli 2018)
    - "[…] not expressly mentioned in the claims of the basic patent, those claims relate necessarily and specifically to that combination. For that purpose, from the point of view of a **person skilled in the art** and on the basis of the **prior art** at the **filing date or priority date** of the basic patent:

      - the combination of those active ingredients must necessarily, in the light of the description and drawings of that patent, fall under the invention covered by that patent, and

      - each of those active ingredients must be specifically identifiable, in the light of all the information disclosed by that patent."

3. VILKÅRENE FOR Å FÅ MEDDELT ET SPC

- Art. 3 (a) the product is protected by a basic patent in force;
  - Hva hvis kravet omfatter «a funtional definition» eller «a Markush formula»
    - C-650/17 og C-114/18 *Royalty Pharma* og *Sandoz/Hexal*
      - AG Hogans opinion 11. september 2019 avsnitt 78:
        - Bekrefter C-121/17 *Teva*
        - Art. 3 (a) "does not preclude (…) a functional definition or a Markush formula"
        - "The concept of the "core inventive advance" of the patent does not apply and is of no relevance in the context of Article 3 (a)"

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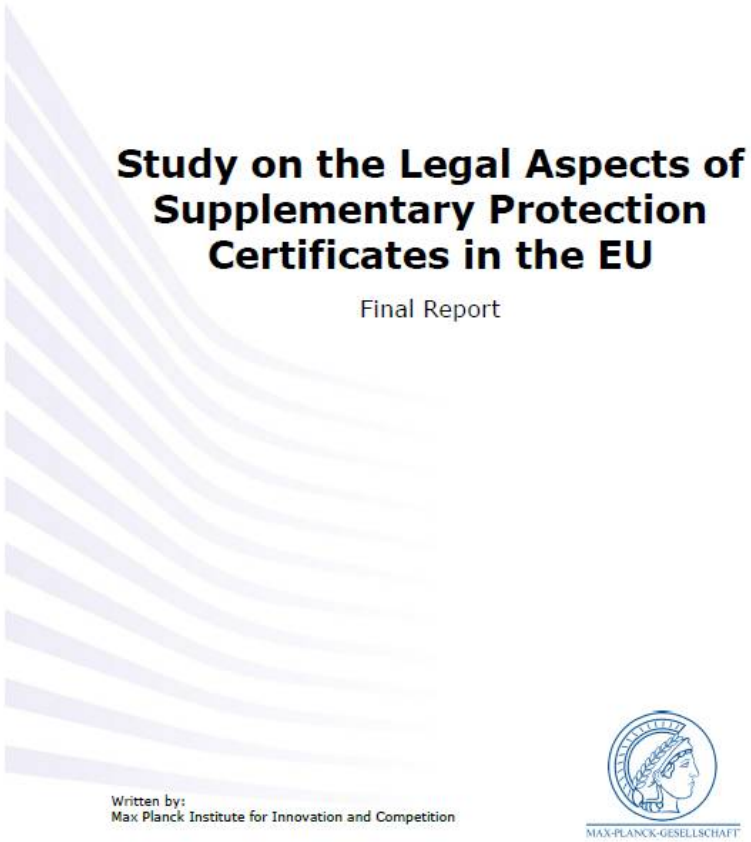
4. VEIEN VIDERE?



4. VEIEN VIDERE?

- Max Planck Institutes rapport 28. mai 2018
  - 746 siders rapport
  - 780 sider annex
  - 33 anbefalinger

4. VEIEN VIDERE?

- Max Planck Institutes rapport 28. mai 2018
  - Recommendation No 1: Consolidated version of the Medicinal Products Regulation
  - Recommendation No 2: Reference to national law
  - Recommendation No 3: Updated definition of the term "medicinal product"
  - Recommendation No 4: Definition of the term "product"
  - Recommendation No 5: SPC eligibility of salts, esters or derivatives of an active substance
  - Recommendation No 6: Concept of MA
  - Recommendation No 7: Clarification of Art. 3(a) Reg. 469/2009 and Reg. 1610/96

4. VEIEN VIDERE?

- Max Planck Institutes rapport 28. mai 2018
  - Recommendation No 8: Art. 3(a) and process patents
  - Recommendation No 9: Art. 3(b) Reg. 469/2009
  - Recommendation No 10: Closing the gap between the wording of Art. 3(d) Reg. 469/2009 and the case law (*Neurim* and *Abraxis*)
  - Recommendation No 11: Closing the gap between the wording of Art. 3(c) Reg. 469/2009 and the case law (*AHP*; *Biogen*)
  - Recommendation No 12: Art. 3(c) Reg. 469/2009 and surrender/revocation of the certificate
  - Recommendation No 13: Entitlement to SPC and third-party MA issue

4. VEIEN VIDERE?

- Max Planck Institutes rapport 28. mai 2018
  - Recommendation No 14: Clarifying the status of the product description and its impact on the scope under Art. 4 Reg. 469/2009
  - Recommendation No 15: Biological products – soft law clarifying the scope
  - Recommendation No 16: Drug/medical device combinations
  - Recommendation No 17: Manufacturing waiver – policy options to be considered
  - Recommendation No 18: *Bolar* exemption – defining a unitary scope of the exemption
  - Recommendation No. 19: *Bolar* exemption and plant protection products

4. VEIEN VIDERE?

- Max Planck Institutes rapport 28. mai 2018
  - Recommendation No 20: *Bolar* exemption and experimental use – third-party suppliers
  - Recommendation No 21: Plant protection products – updating the reference to the regulatory framework
  - Recommendation No 22: Plant protection products – provisional MAs
  - Recommendation No 23: Art. 13(3) Reg. 1610/96
  - Recommendation No 24: Guidelines for the examination
  - Recommendation No 25: Further unification of the SPC framework
  - Recommendation No 26: Interaction between Unitary Patent Regulation and SPC legislation

4. VEIEN VIDERE?

- Max Planck Institutes rapport 28. mai 2018
  - Recommendation No 27: Creation of a unitary SPC system
  - Recommendation No 28: Institutional aspects
  - Recommendation No 29: Substantive provisions – Art. 3(b)
  - Recommendation No 30: Substantive provisions – Art. 3(c)
  - Recommendation No 31: Substantive provisions – Art. 3(d)
  - Recommendation No 32: Duration of the unitary SPC – Art. 13
  - Recommendation No 33: Procedural aspects – function of the granting office in appeal procedures

4. VEIEN VIDERE?

- Max Planck Institutes rapport 28. mai 2018
  - Recommendation No 17: Manufacturing waiver – policy options to be considered

- Forordning (EU) 2019/933 20. mai 2019
  - Manufacturing waiver for export
    - Eksport utenfor EU (EØS)
  - Manufacturing waiver for stockpiling
    - 6 måneder før utløpet av SPC

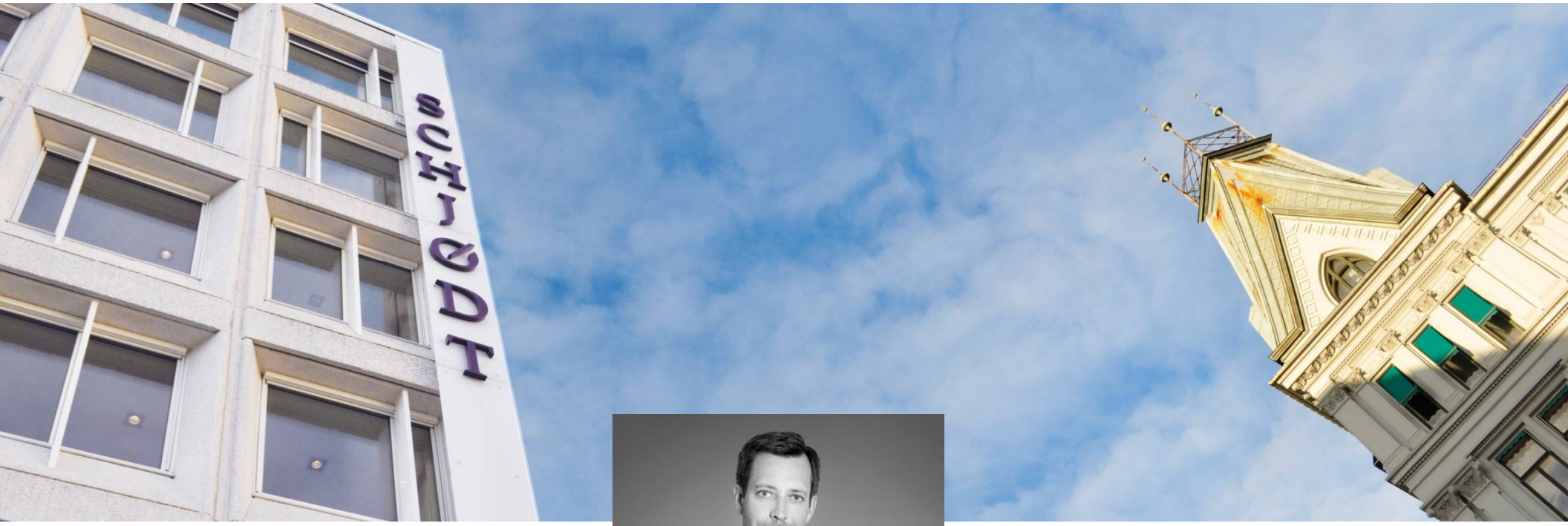
4. VEIEN VIDERE?

- EU-kommisjonen
  - Pågående evaluering
    - Single grant mechanism
    - Unitary title
    - Subject to discussions

4. VEIEN VIDERE?

- PhD-student Ulla Callesen Klinge
  - Supplementary Protection Certificates (SPC)

4. VEIEN VIDERE?



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