

# HØIBERG Patent School

## Freedom To Operate - how to ensure market access ?

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# Moderator



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# Practical information

- **The webinar is recorded**
  - Available on our webpage within the next couple of days
  - All participants are kept anonymous in the recording
- **Please ask any questions in the “Q&A”- box**
  - Questions will be answered at the end of the webinar unless a specific question requires “immediate attention”
- **15-20 second time lag**
  - Questions are received in real-time but answers/comments will come with a delay

# Speakers



## **Jens Viktor Nørgaard**

Partner, Head of Biotechnology & Plant Sciences, European Patent Attorney

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## **Charlotta Dahlborg**

Patent Attorney and Business developer

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# Agenda

- **What is Freedom to Operate (FTO)?**
- **What is the difference between having a patent and having Freedom to Operate?**
- **How to determine Freedom to Operate?**
- **Different types of infringement?**
- **Different geographic markets?**
- **How to ensure market access?**

# Patents are prohibitive

Monopoly

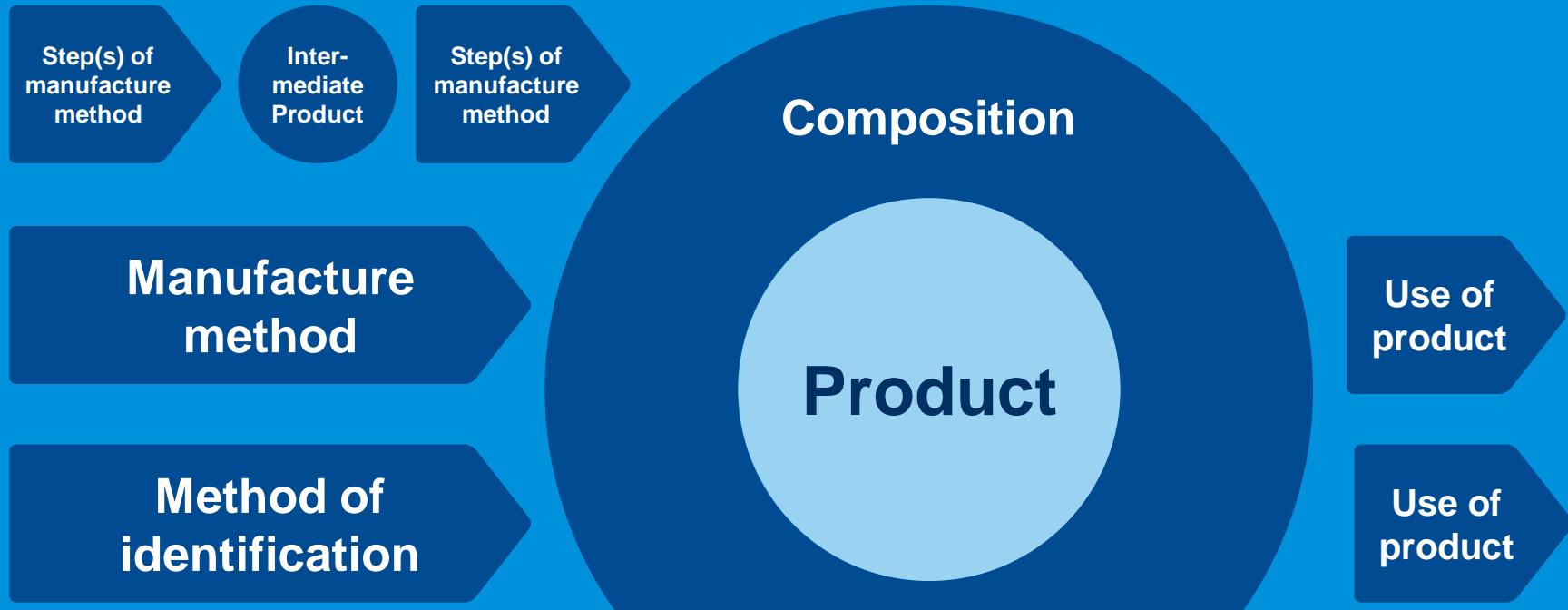
Right to forbid others to exploit the invention

The right is defined in the claims

The right arises, when the claims are granted (B - publications)



# Types of Technology



# Patentability - Requirements



Patentable subject matter

No. 223,898.

T. A. EDISON.  
Electric-Lamp.

Patented Jan. 27, 1880.



Novel



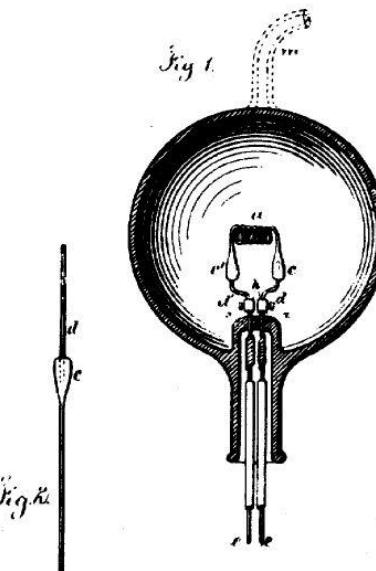
Inventive / non-obvious



Industrially applicable (useful)



Sufficient description



# Freedom to Operate (FTO)

- Is there market access?
- Direct market access is present when there are no dominating patent rights.
- A dominating right may cover all, or just a small part of the product you wish to market.



# Patentability vs Freedom to Operate

## Patentability

Relates to your patent rights (IPR)

### Key Question

Are the claims in my patent application patentable?

## Freedom to Operate

Relates to your product or service (what you sell)

### Key Question

Does my product/service infringe others' patents?

# Patentability vs FTO

Focus on the "invention"

One novel feature required, then everything can be claimed

Prior art includes everything

Global criteria

Only relevant for patent active companies

Focus on the product / process

All steps, components, ingredients are relevant

Only patents matter

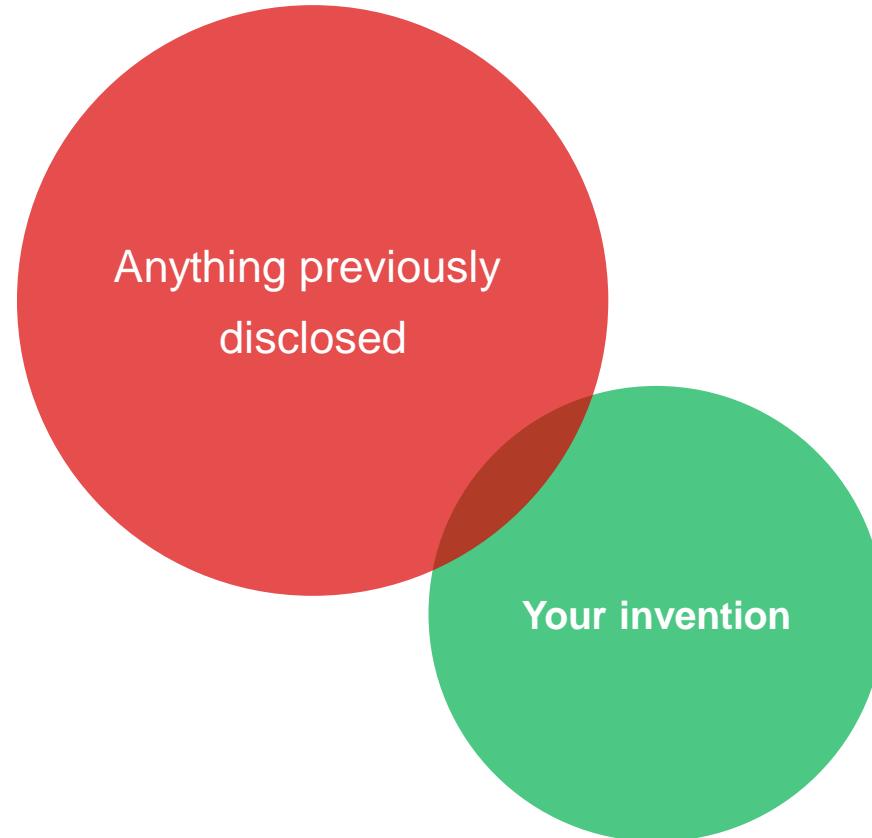
Depends on geographic market

Relevant for **all** companies

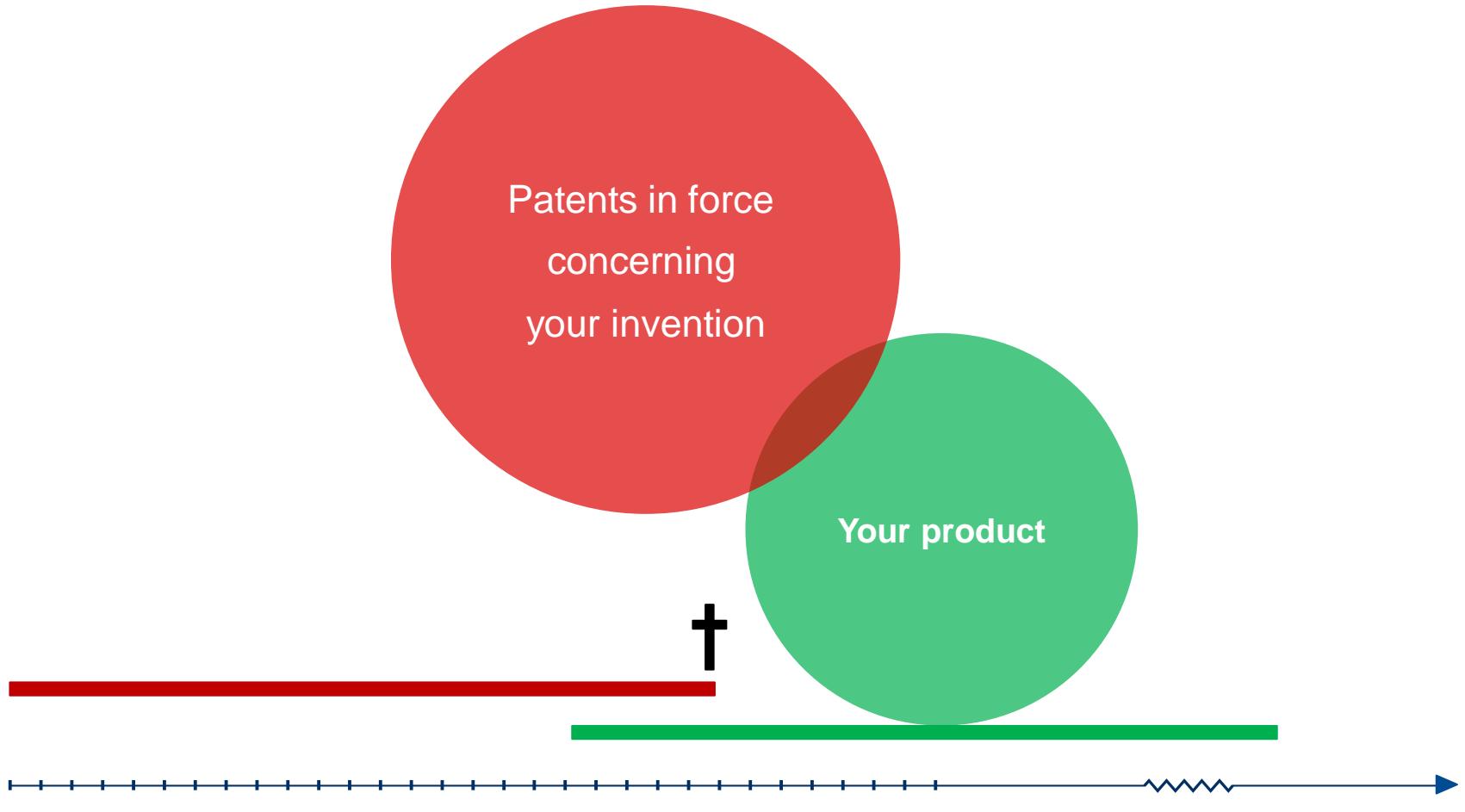
# Your product



# Patentability – Prior art



# FTO – Dominating rights



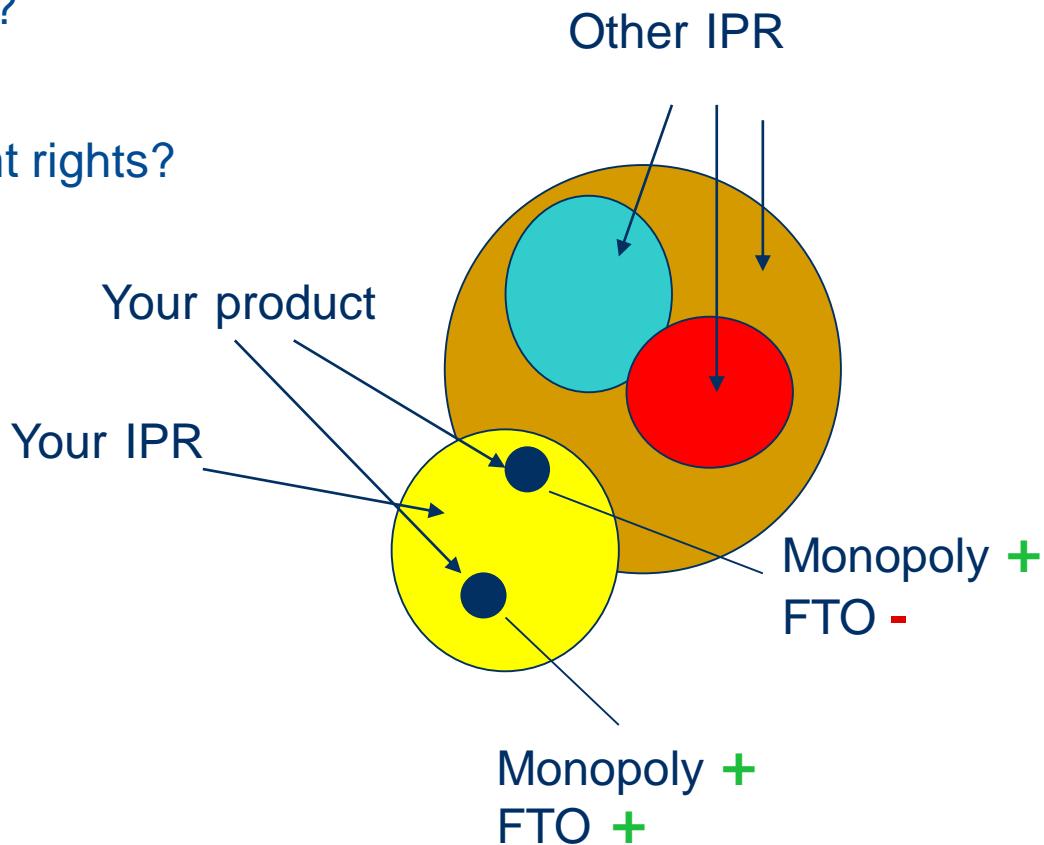
# Freedom-to-operate (FTO)

Do you have Freedom-to-operate?

- How about competitors' patent rights?

Why FTO?

- Risk management
- Estimation of value



# Freedom-to-operate - general

Questions:

- What is to be commercialised – be as specific as possible
- When will it be commercialised – patents last for 21\* years (only!)
- Where will it be commercialised – patents are national rights
  - \*with a few notable exceptions beyond 21 years.



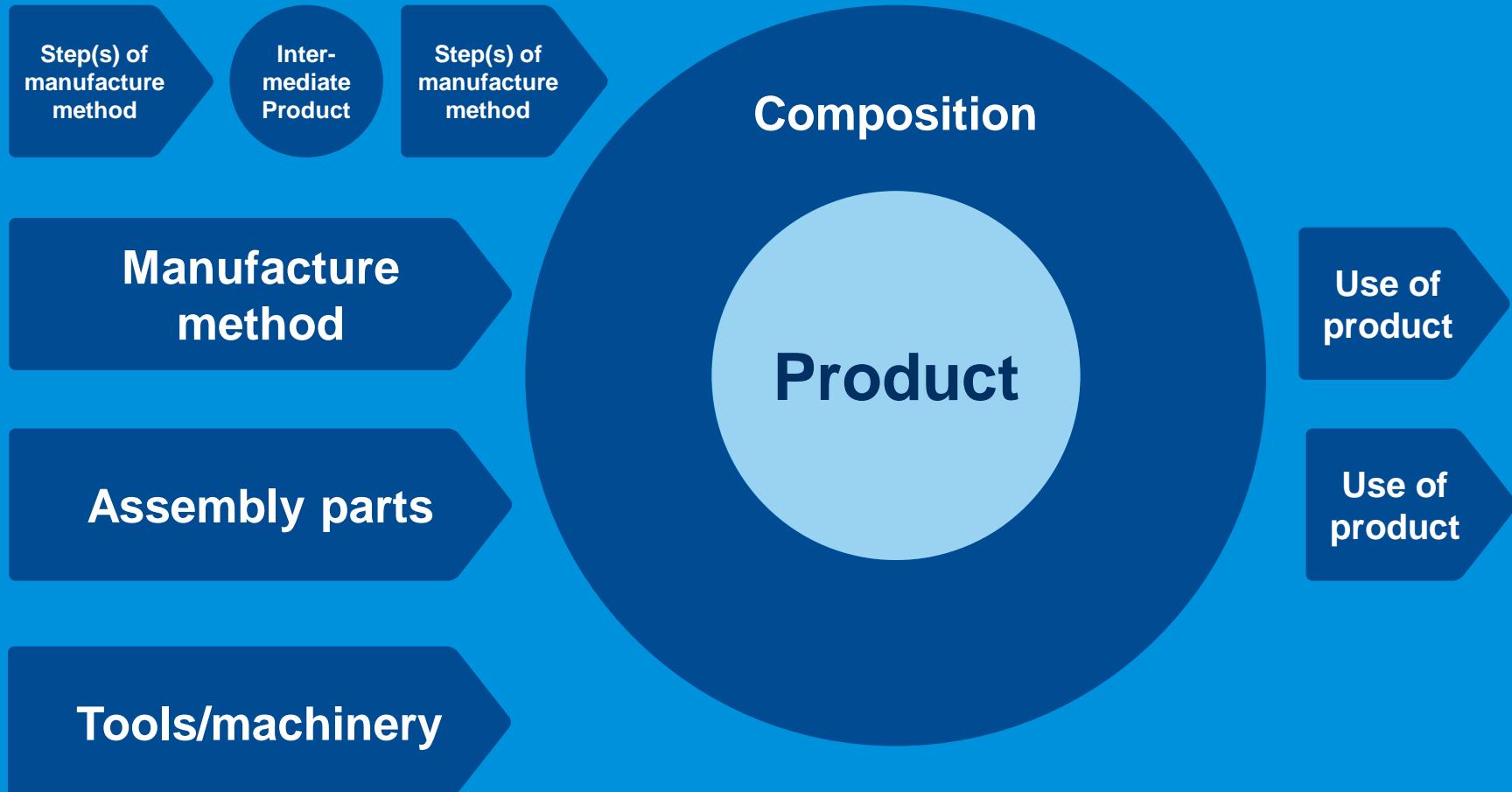
# Checklist for your Business Plan

- **How will you ensure exclusivity?**
  - Which inventions/patents?
  - Ownership – how has company acquired the right to the patent?
  - Geographic strategy and why?
- **How will you check for freedom to operate?**
  - What is your product/service?
  - Is it final or is there still room for changing it?
  - What are your markets?
  - When do you expect to be on the market?
  - Which analyses will you get done and when?

# Your product



# Elements of your product



# Your product

Parts

Characteristics



Manufacturing and  
assembly

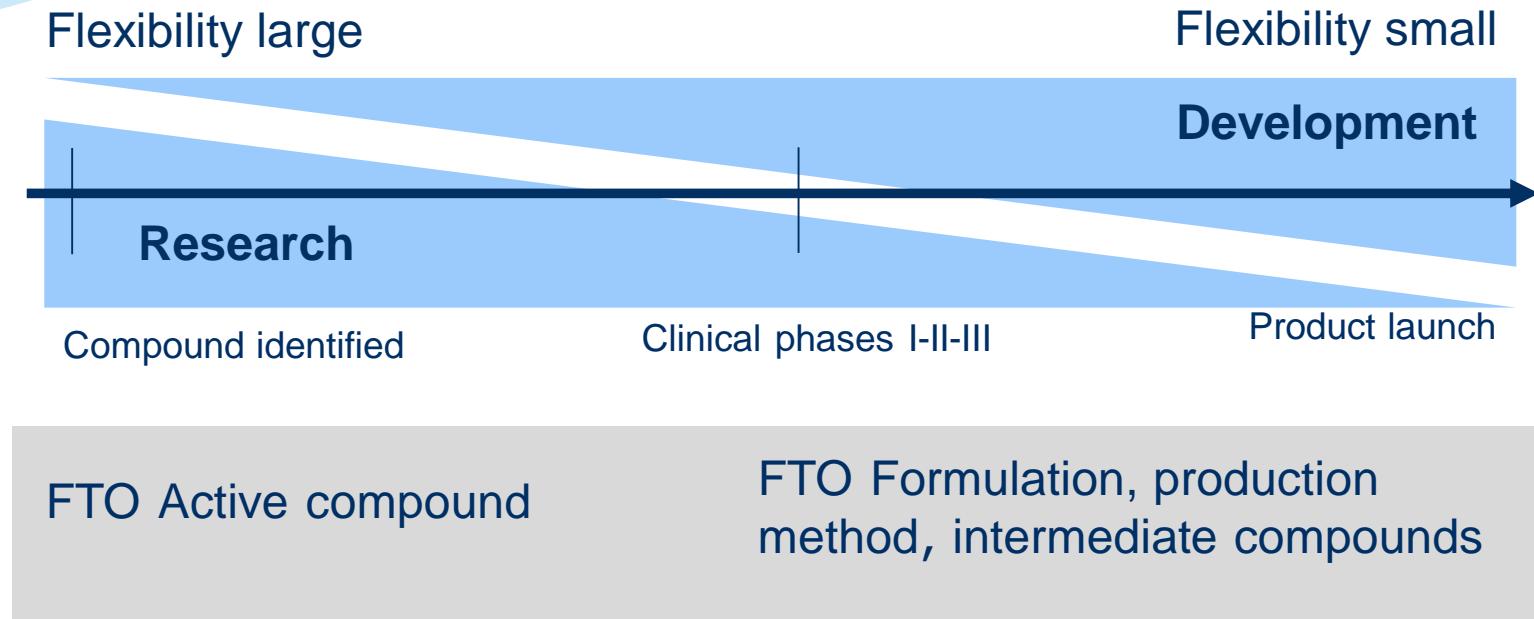
Tools and  
methods

Parts and  
ingredients

# Freedom-to-operate – general

## Timing

- A FTO analysis to the generic principle as early as possible
- FTO updates for each more specific product to be commercialised before decisions regarding the final product/method are made



# Type and Extent of FTO

FTO depending on development stage

Target search

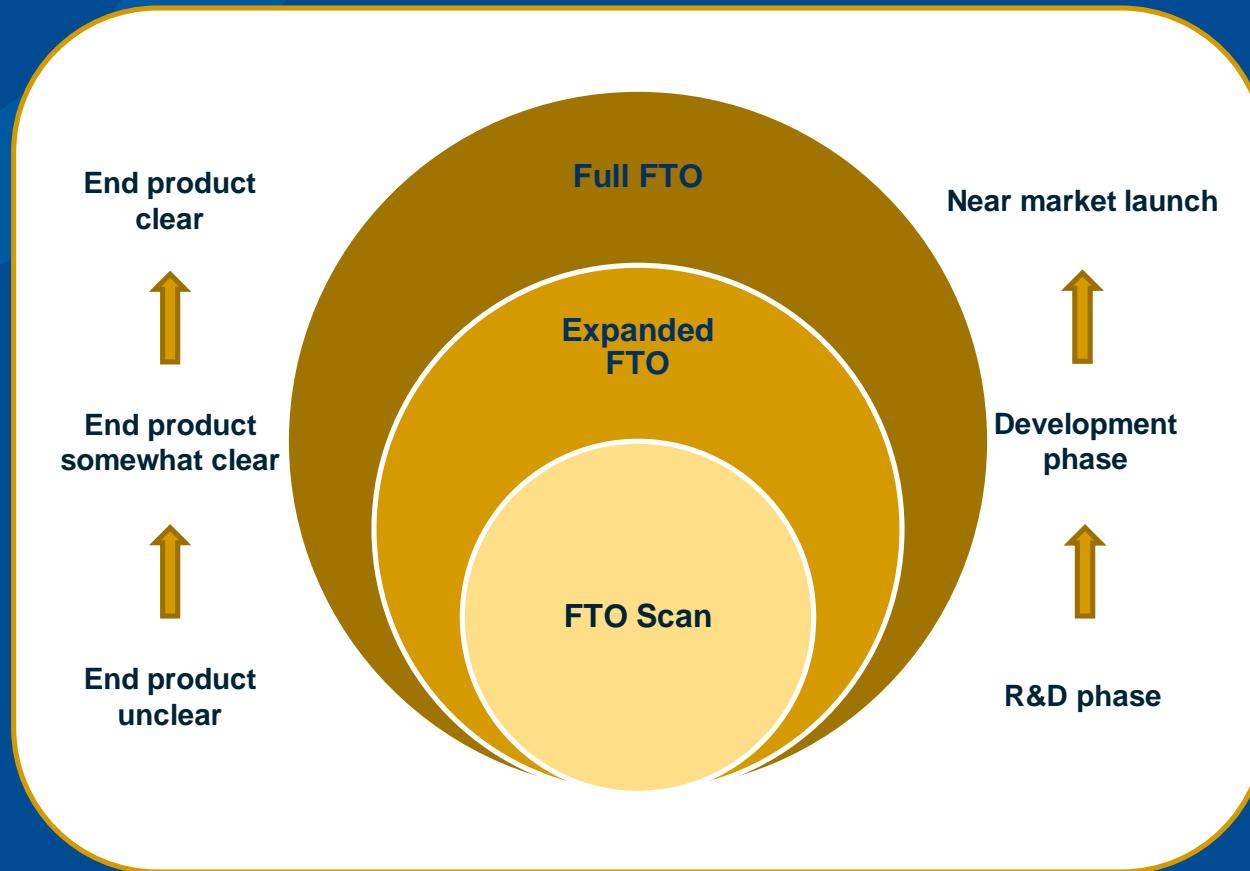
Patent landscape – find sweet spots

Find show-stoppers

Product development

- Idea generation
- Target identification
- Lead generation, prototyping
- Fine tuning

# Let the risk analysis follow development



# FTO Procedure

# FTO input parameters

- Product description
- Description of manufacturing
- Description of intended use
- Geographical market
- Manufacturing – where
- Distribution – where
- Time of market entry

# Freedom-to-operate

- FTO analysis
  - 1. Search for patent rights
  - 2. Look at patent expiry
  - 3. Evaluate scope of protection for the identified patent rights for each country
  - 4. Evaluate validity of potentially dominating patent rights
  - 5. Investigate possibility of licensing dominating patent rights

# FTO Procedure

## 1. Search

Planning the search to find potentially dominating patent rights

- Determine relevant markets
- Determine relevant timing of marketing
- Determine search strategy (e.g. broad vs. narrow scope)
- Search phrases
- Database choices
- Database searching and manual filtration of results

# FTO Procedure

## 2. Analysis

Analysis of identified patent rights

- Status (is the patent in force?)
- Calculation of expected duration and possible patent term extenions

Assessment of scope of protection

- Patent claims
- Aspects of the specification / description of the patent
-

# First Hit Sorting Round

- Do the identified patents have an expiry date pre-dating the date of market entry?
- Have the patents been filed in the relevant markets?
- If yes, are they in force?
  - Have they been granted?
  - Have the annuities been paid?
  - Are any divisionals pending?

# Legal Status

- Patent / patent application lapsed due to:
  - non-payment of annuity
  - non-payment of other fees (issue fee, examination fee, etc.)
  - non filing of response to office action
  - not filing national stage application
- Has it really lapsed? Completely? Finally? No chance of reinstating?

# FTO Procedure

## 3. Patentability of dominating rights

### Patentability assessment

- Novelty search
- Analysis of novelty and inventive step / obviousness
- Analysis of case history
- Analysis of oppositions and court cases (infringement / invalidity cases)
- Analysis of formal grounds of invalidity

# Infringement

# Direct infringement



- Claim 1:  
Chair, comprising
  - a. 4 vertical support elements
  - b. 1 horizontal plate element

# Direct infringement



- Claim 1:  
Chair, comprising
  - a. 4 vertical support elements
  - b. 1 horizontal plate element

# Direct infringement ?



- Claim 1:  
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# Direct infringement ?



- Claim 1:  
Chair, comprising
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  - b. 1 horizontal plate element

# Indirect infringement - Inducement to infringe



- Claim 1:  
Chair, comprising
  - a. 4 vertical support elements
  - b. 1 horizontal plate element

# Infringement - concept 1



- Claim 1:  
Chair, comprising
  - a. 4 vertical support elements
  - b. 1 horizontal plate element

# Direct infringement - concept 2



- Claim 1:  
Chair, comprising
  - a. 4 vertical support elements
  - b. 1 horizontal plate element
  - c. armrest

# Direct infringement - concept 3



- Claim 1:  
Storage device for TV remote control,  
comprising
- b. 1 horizontal plate element
- c. lifted 20-30cm above seating level

# Direct infringement - technology



- Claim 1:  
PU Foam material from the reaction product of X and Y at 72°C ....

# Direct infringement - method of manufacture



- Claim 1:  
Method of uniting two element comprising the steps of
  - a. providing a projection on the first element
  - b. providing an aperture in the second element essentially the shape of the projection of the first element
  - c. placing the projection in the aperture

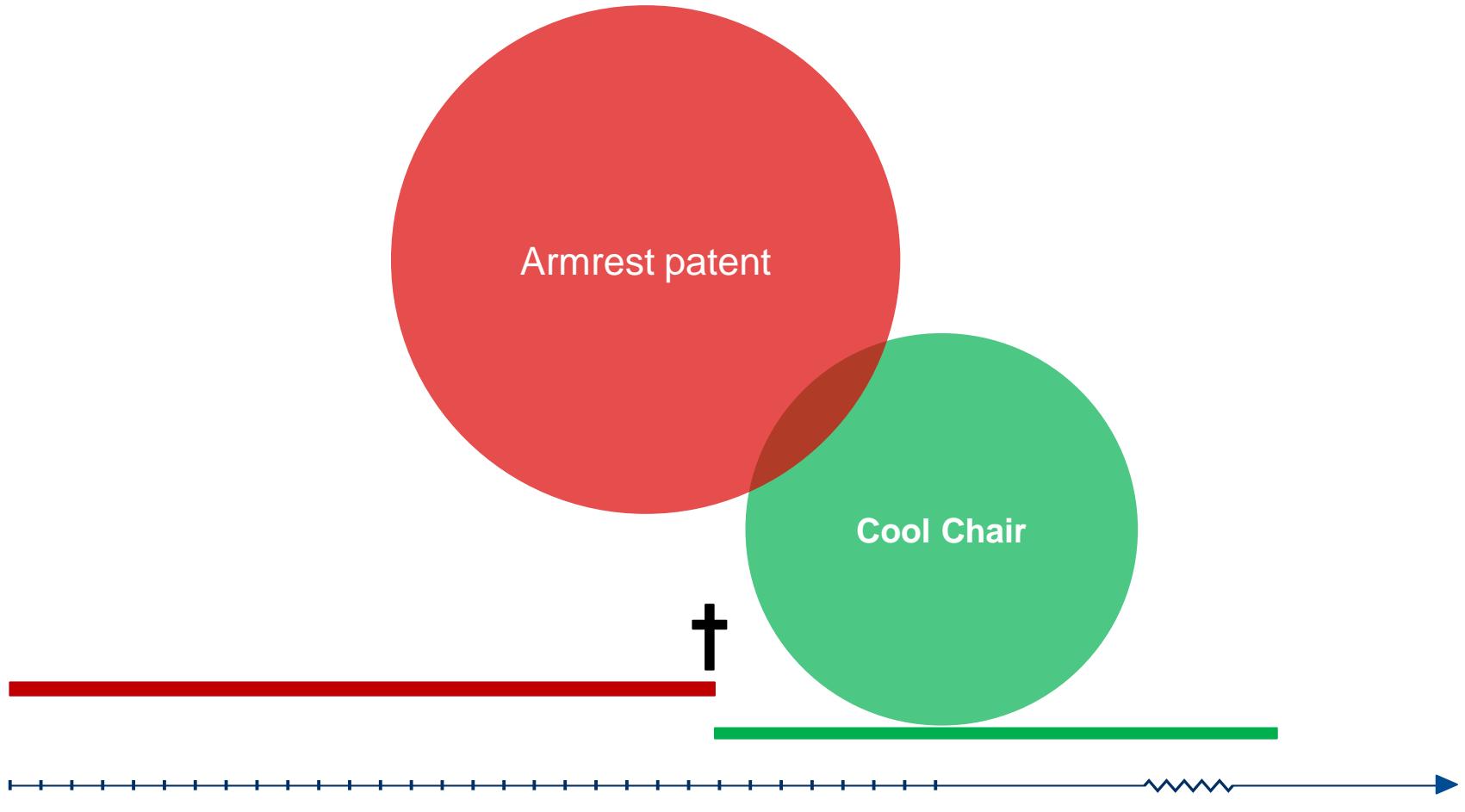
CHARACTERIZED IN THAT the projection is longer than it is wide

# What is a chair?



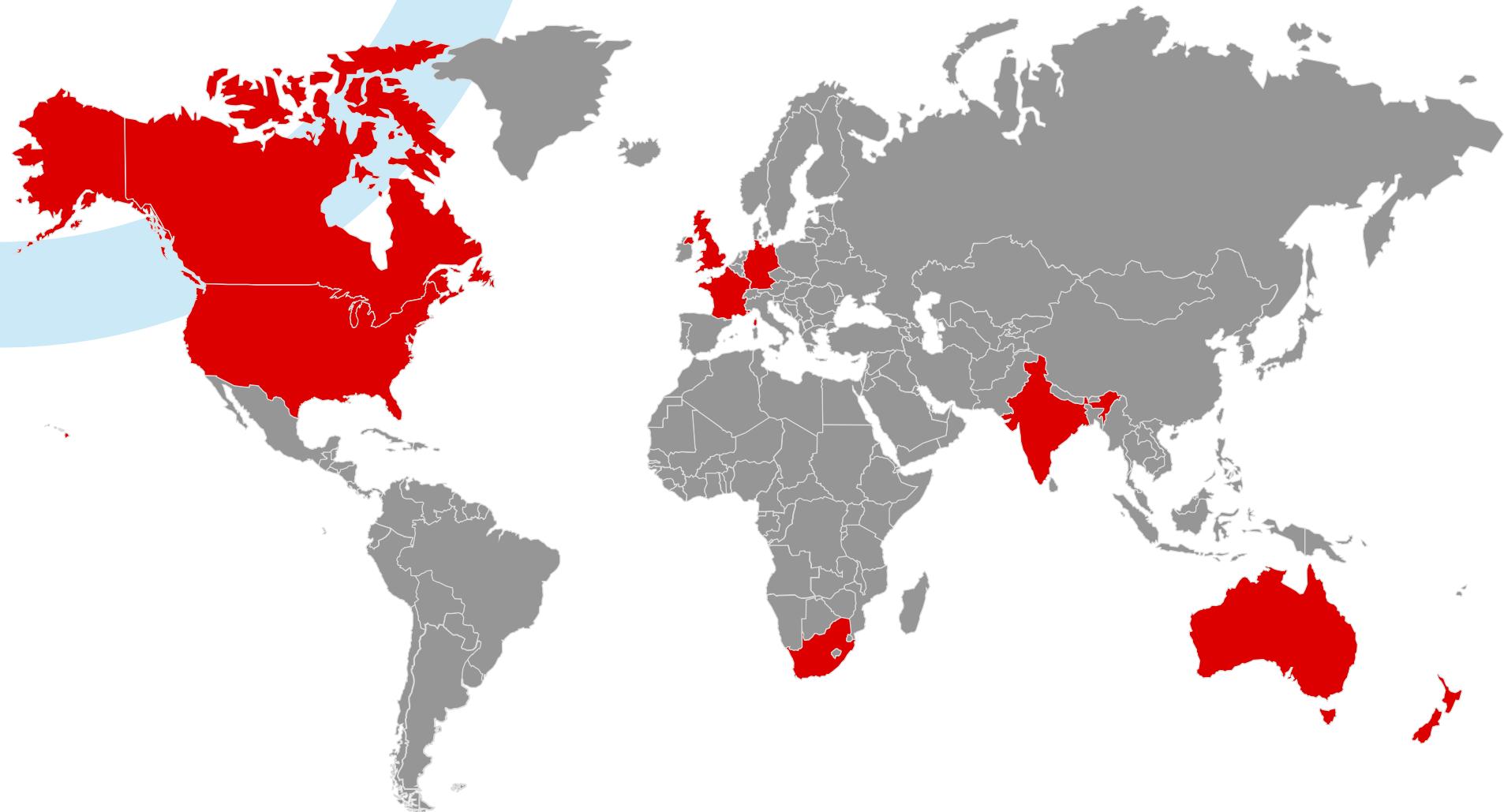
# Time

# FTO – Dominating rights

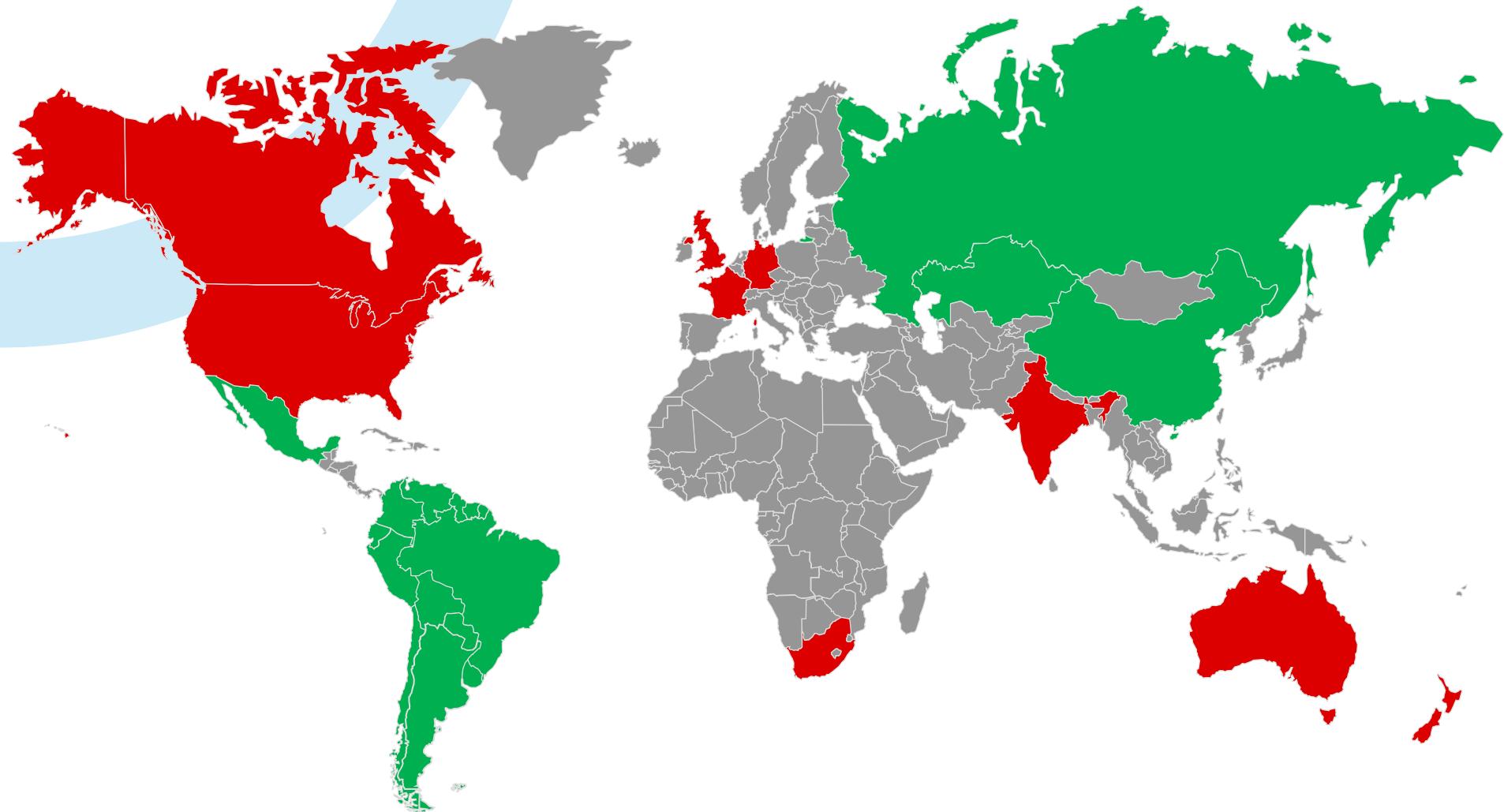


# Geography

# FTO - Geography



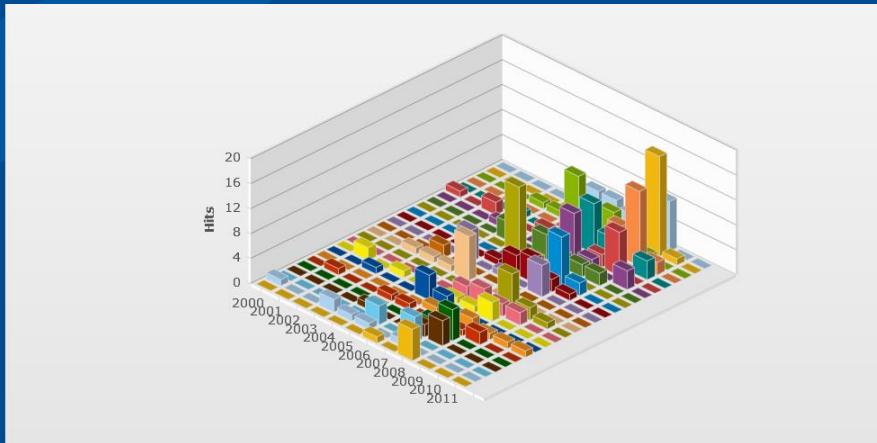
# FTO - Geography



# How to get market access?

# Market access considerations

- Considerations:
  - What is the landscape of competitors' patent rights?



- Is it possible to design around when optimizing the product?
- Are licenses to third party patent rights nice to have or need to have?

# Business Considerations

Who is the patent proprietor?

- University
- Competitor
- Non-competing company

# Types of patent licenses

## Exclusive Licenses

Allows only one licensee to benefit from the licensing agreement

The licensor remains the owner of the patent.

May also include the enforcement rights (all substantial rights) of the patent  
→ licensee can sue infringers.

## Non-Exclusive Licenses

Allows multiple licensees to produce the invention, design, or technology

## Partially Exclusive Licenses

Partially exclusive licenses grant exclusivity to certain applications of a patent  
→ geographic limitations, or a  
→ term period

## Cross-licenses

Allows to parties to license each other's inventions.

# Active Steps

Design around

Delay market entry

Merger or Acquisition

Joint venture

Opposition, re-examination, post-grant review, invalidity complaint, declaratory judgement

# Q&A

# Thank you!

A recording of this webinar will be available on <https://hoiberg.com>

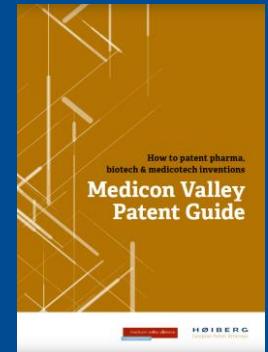
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