



Exceptions to Patentability

What cannot be done

Jens Viktor Nørgaard
01.02.2017

 HØIBERG European patent & trademark attorneys

Speaker / CV



Jens Viktor Nørgaard

Head of Biotechnology & Plant sciences
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 HØIBERG European patent & trademark attorneys 01.02.2017

Agenda

Stem cells
Plant varieties
Products of nature
Laws of nature
Abstract ideas

Why Exceptions



- Ethics, morale
- Non-technical
- Alternative types of protection
- Courts' interpretation of the law
- Public/lobbyist pressure

East meets West

USA

Common law country

Governed by

- the law
- Court interpretation

Europe

Legislator decides

Governed by

- Ethics
- No double protection

Stem cells (European Exemption)

- The law:
- No patents on:
 - Processes for cloning human beings
 - Processes for modifying the germ line genetic identity of human beings
 - Uses of human embryos for industrial or commercial purposes

Stem Cells

- Board of Appeal of EPO, German Courts and European Court of Justice have decided that an embryo encompasses a fertilised human egg, i.e. a stem cell
- Patents on stem cells are invalid if generation of stem cells require “destruction of human embryos”

Light at the end of the Tunnel?

- Stem cells can be generated by single-cell biopsy from embryo.
- Not destruction of human embryo
- Stem cell patents after that this technology was developed are valid

Plant Varieties

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Plant Varieties - Background

New plant varieties can be Protected (UPOV; CPVO)

European exception

Breeder's & farmer's privilege

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Plant Varieties (European Exception)



- Patents are not granted on plant and animal varieties.
- Patents are not granted on “essentially biological processes for production of plants”
- “Essentially biological processes” involve “entirely natural phenomena such as crossing and selection” - sic

Plant Varieties – European Status

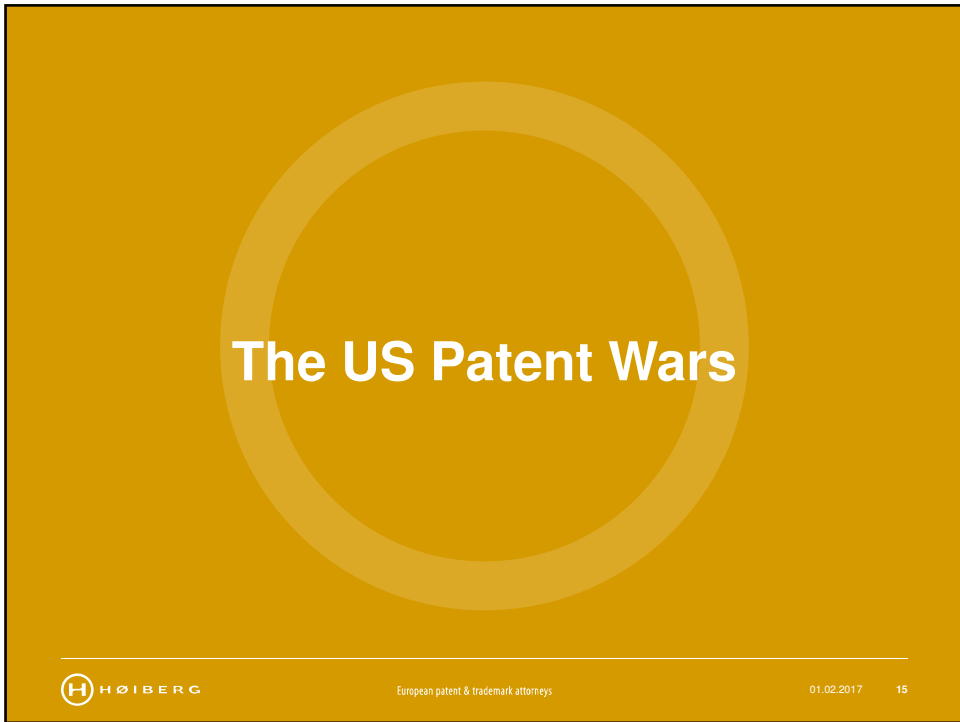
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- Claims can encompass plant varieties
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European Status – or perhaps not

- European Commission has interpreted the “intention” of the legislator of the Biotech Directive.
- According to the Commission, the intent was not to allow patents on plant or animal varieties obtained by “essentially biological processes”.
- EPO has stayed proceedings in all relevant cases....
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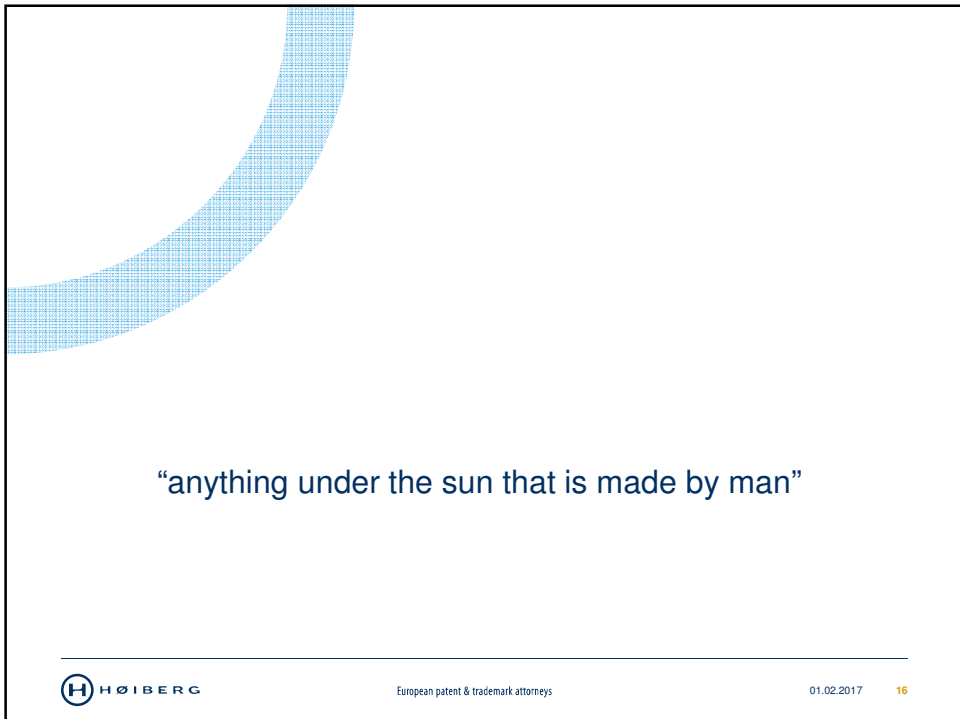
Europe – lack of Harmonisation

- Different rights floating from plant patents
- Holland: The breeder has a right to a license to “Plant patents”
- Germany: Complete freedom to use patented plants for breeding
- Denmark, etc: no special rights for plant breeders




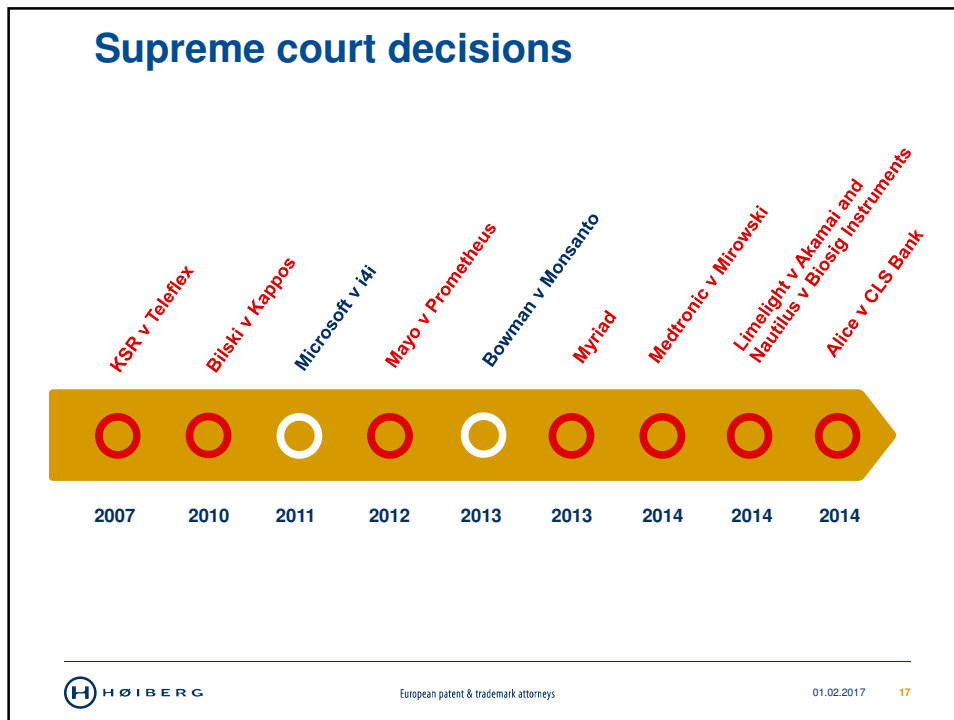
The US Patent Wars

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“anything under the sun that is made by man”

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What does the law say

Patent eligible subject matter (§ 101):
 Whoever invents or discovers any new and useful
process,
machine,
manufacture, or
composition of matter, or
 any new and useful improvement thereof, may obtain a patent
 therefor, subject to the conditions and requirements of this title.

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Mayo vs. Prometheus

- Prometheus Labs had rights to a series of US patents directed to a diagnostic method.
- The method involved:
 - Determining the level of metabolites of thiopurines
 - Wherein the level indicates a need to increase or decrease the amount of drug to be administered.
- Prometheus sued Mayo Medical Laboratories for infringement of their US patents

Mayo vs. Prometheus


There is a danger that granting patents that tie up use of laws of nature will inhibit future innovation

Provides incentives that lead to creation, invention and discovery

Patent protection is a two-edged sword


Consequences

- No diagnostic patents are granted
- Diagnostic correlation = "law of nature"
- The detection method must be patentable in itself

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Myriad

- Myriad Genetics proprietor to a number of US patents
- Patent claims:
 - "isolated" human deoxyribonucleic acid (DNA) sequences "BRCA1" and "BRCA2"; and
 - mutations associated with predisposition to breast and ovarian cancers

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Myriad

- Supreme Court Held that “isolated” stretches of genomic DNA for the BRCA1 gene were not patent eligible
- Products of nature (despite acknowledged chemical differences)
- Groundbreaking, innovative, or even brilliant discovery is not by itself sufficient



Myriad

- It is important to note what is *not* implicated by this decision.
- This case does not involve patents on new *applications* of knowledge about the BRCA1 and BRCA2 genes.
- Patentability of DNA in which the order of the naturally occurring nucleotides has been altered was not considered (cDNA).



Myriad - Consequences

- No patents on naturally occurring products
- Recombinant proteins
- Small molecules
- Microorganisms
- Stem cells
- Dolly the sheep



Living next door to – Alice Corp

*Alice v. CLS Bank Supreme Court Case
Business Method patent.*

Claim 18. A method to enable the formulation of customized multi-party risk management contracts having a future time of maturity, the method comprising the steps of:

Question – is the patent directed to an abstract idea and nothing more

The Alice Test

1) Are the claims directed to a patent-ineligible concept (*e.g.*, an abstract idea)?

2) If so, what else is there in the claim?

• This step is a search for an “inventive concept”—*i.e.*, an element or combination of elements that is “sufficient to ensure that the patent in practice amounts to “significantly more” than a patent upon the [ineligible concept] itself.”

Many diagnostic algorithms fail the Alice test

Examples from Guidelines and Training materials

- Amazonic acid (anticancer drug from plant)
- Pomelo juice with preservative
- Gunpowder

Amazonic acid background

Amazonian cherry tree grows wild in Amazonas

It's leaves contain a substance that has anti-cancer effects

Nobody has succeeded in isolating the compound

Amazonic acid background

Applicant has isolated amazonic acid

Has demonstrated effect in treatment of breast and colon cancer

Has created deoxy amazonic acid, with same activity as amazonic.

Amazonic acid

- Claim 1: Purified amazonic acid
- Claim 2: Deoxyamazonic acid.
- Claim 3: A method of treating breast or colon cancer, comprising: administering an effective amount of purified amazonic acid to a patient suffering from breast or colon cancer.

Patentability Assessment

Claim 1 is not patentable. Separating the acid from its surrounding material in the leaf has resulted in the purified amazonic acid having not markedly different characteristics from its naturally occurring counterpart.

Claim 2 is patentable. The 5-methyl does not exist in nature. The change in structure has not resulted in any different functional characteristics. However, it is patentable because deoxyamazonic acid is a unique molecule that is distinct from, and does not prevent others from using, naturally occurring amazonic acid.

Claim 3 is patentable. The claim is focused on a process of practically applying the product to treat a particular disease (breast or colon cancer), and not on the product *per se*.

Pomelo Juice

1. A composition comprising pomelo juice, and a an effective amount of a preservative.
2. The composition of claim 1 wherein the preservative is 0.5% vitamin E.
3. The composition of claim 1 wherein the pomelo juice is pasteurized.

Pomelo Juice

Claim 1: Patentable. the preservative affects the juice so that it spoils much more slowly (spoil in a few weeks) than the naturally occurring juice by itself (spoil in a few days).

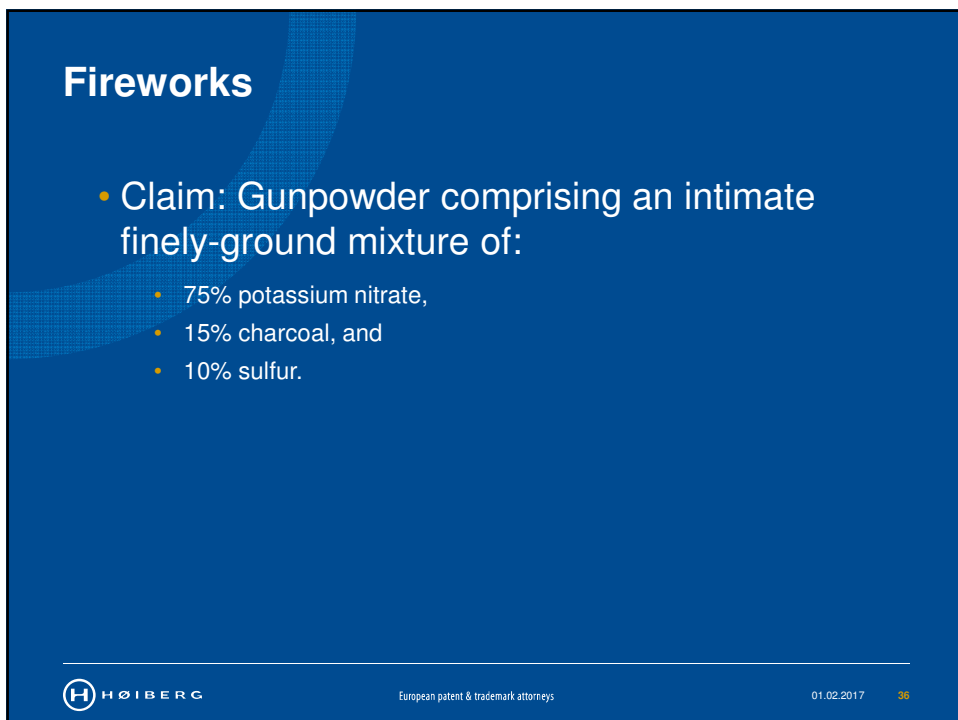
Claim 2: passes the test. X does not occur in nature.

Claim 3: passes the test because the description explains that pasteurizing the juice changes the chemical composition (and uses a big machine)




Gunpowder

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Fireworks

- Claim: Gunpowder comprising an intimate finely-ground mixture of:
 - 75% potassium nitrate,
 - 15% charcoal, and
 - 10% sulfur.

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We have an Invention!

This claim is patentable.

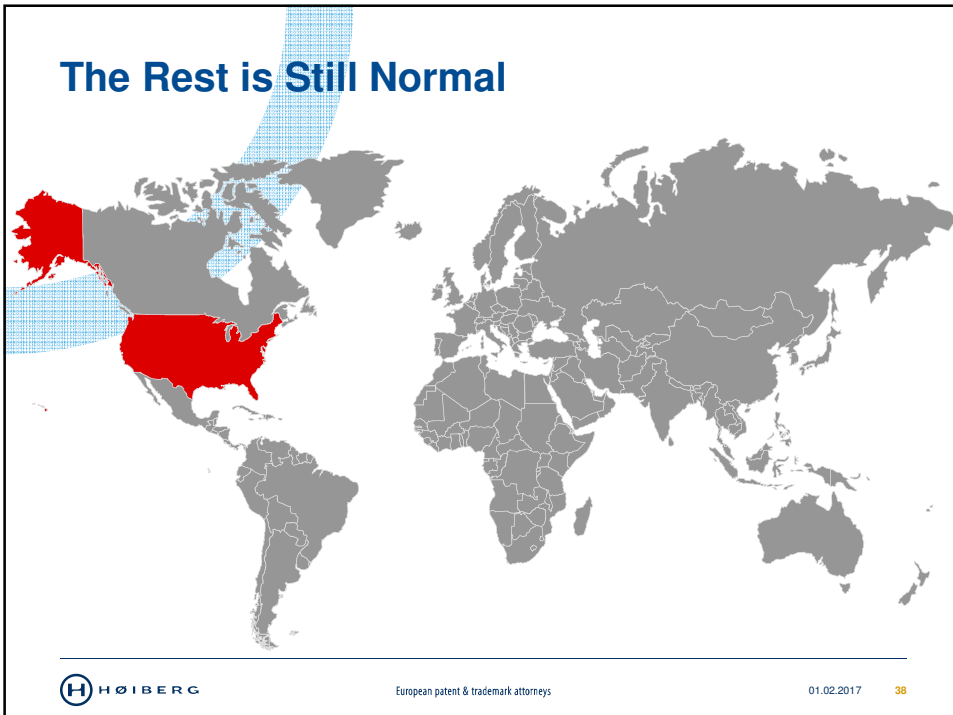
Look at the combination.

The components do not occur together in nature.

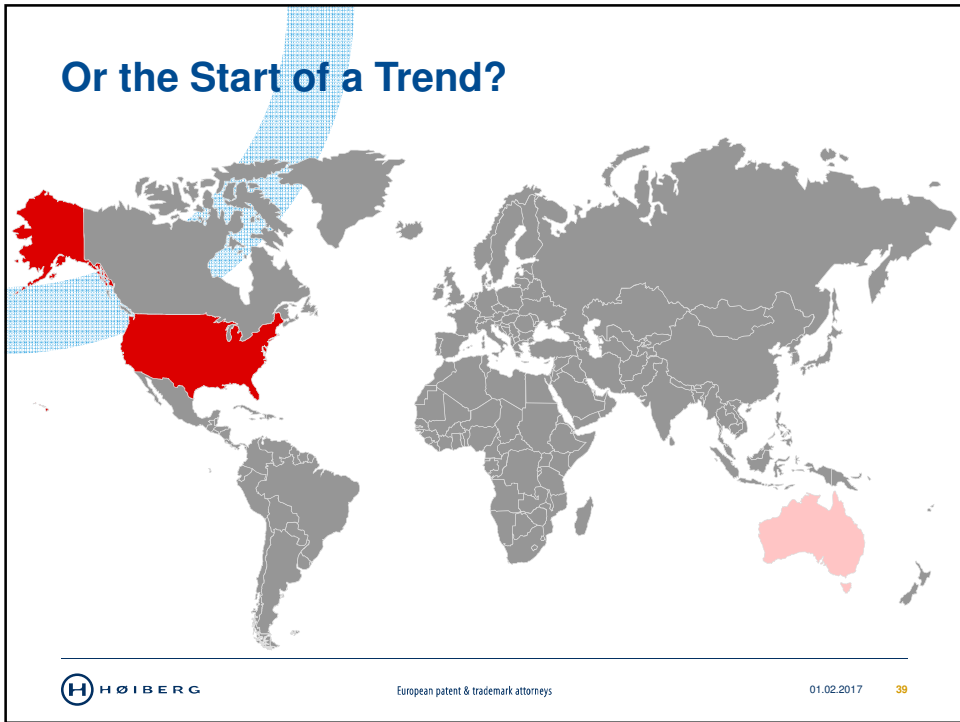
None of the three claimed substances are explosive in nature.

This explosive property of the claimed combination is markedly different from the non-explosive properties of the substances by themselves in nature

The Rest is Still Normal



Or the Start of a Trend?



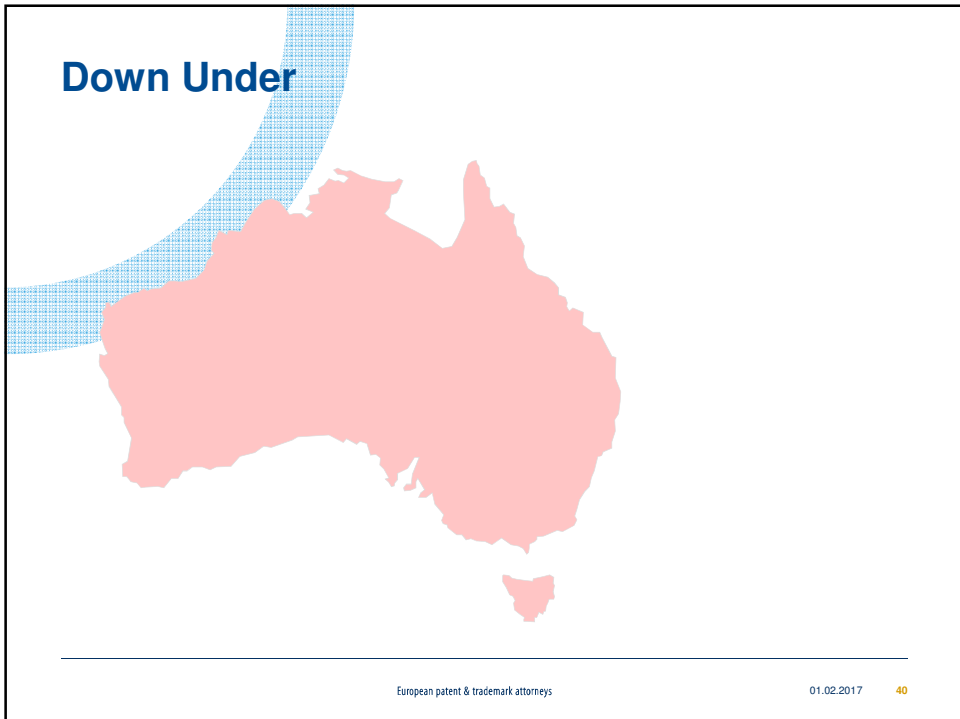
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Recent Decision from AU High Court


- Myriad Genetic's Australian patent on BRCA1 and BRCA2 mutations.
- Claims to isolated DNA: not patentable
- Vectors, probes: patentable
- Diagnostic methods: patentable

Guidance from AU Patent Office

- Proteins and peptides are patentable
- Isolated small molecules (amazonic acid) are patentable
- Diagnostic methods are patentable
- Methods of treatment are patentable



Diagnostics


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Diagnostics

Focus on new and patentable analytical methods

Measure the marker using MS, HPLC or similar "high tech"

Recite all steps of analytical method (e.g. PCR, Elisa)

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Diagnosis

Tie the diagnostic method to treatment, follow-on diagnostics

e.g. add a method of treatment step at the end (if tested positive for condition X, treat with drug Y)

Argue that the additional steps are not routine and conventional. If the claim is non-obvious, it should be patentable.

Compound patents

Compound patents

Add synthesis claims – recombinant or synthetic

Add mutant/derivative/conjugate claims

Do not look for mutants/derivatives in nature

Add method of treatment claims

Other Exceptions in General

- Business methods
- Computer programs "as such"

India

- No patents on plants, seeds, or animals
- No patents on drug formulations
- No patents on salts
- No patents on new use of known compound
- No patents on products isolated from nature

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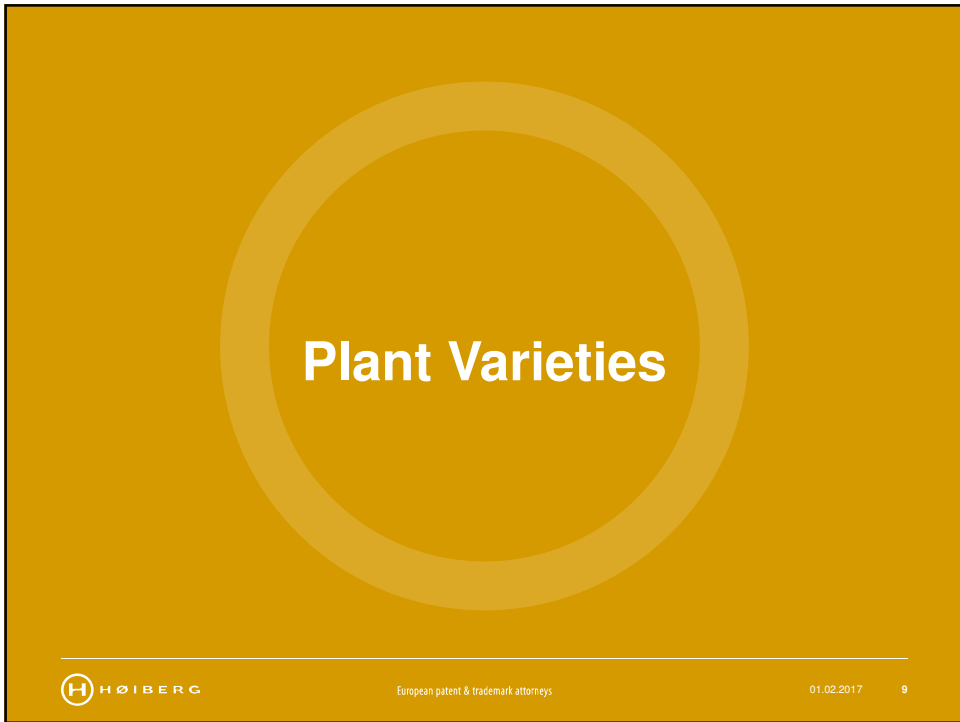
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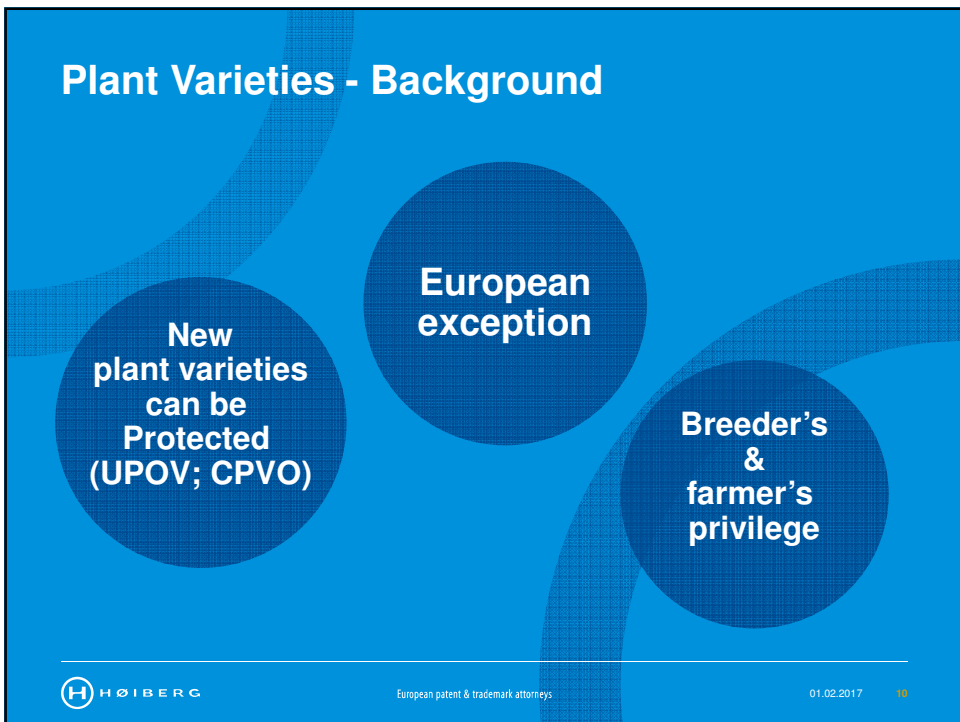
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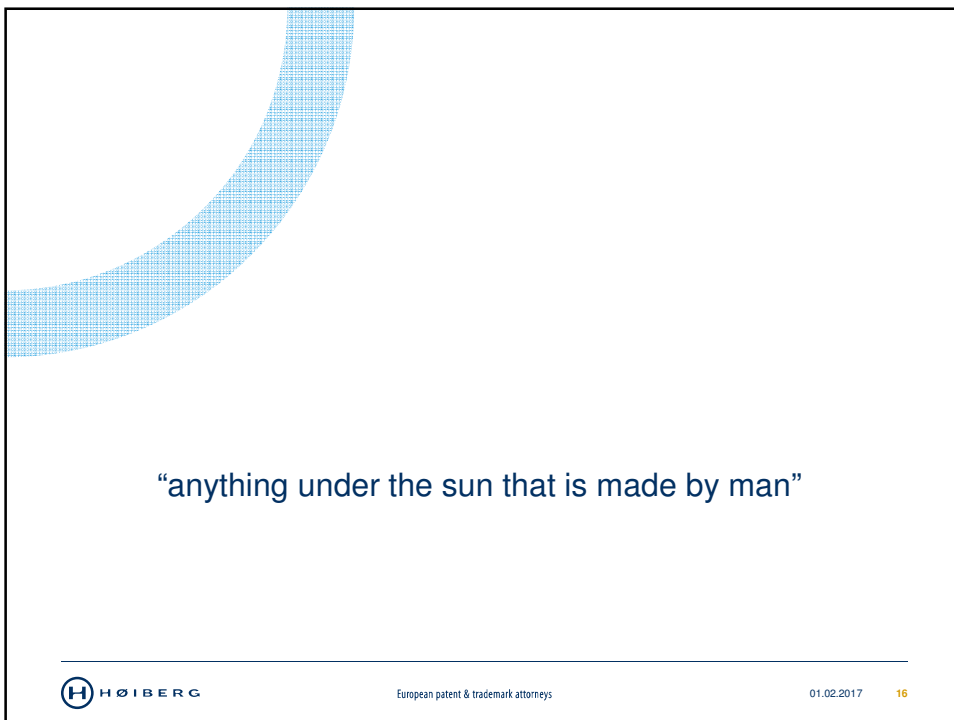
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The US Patent Wars

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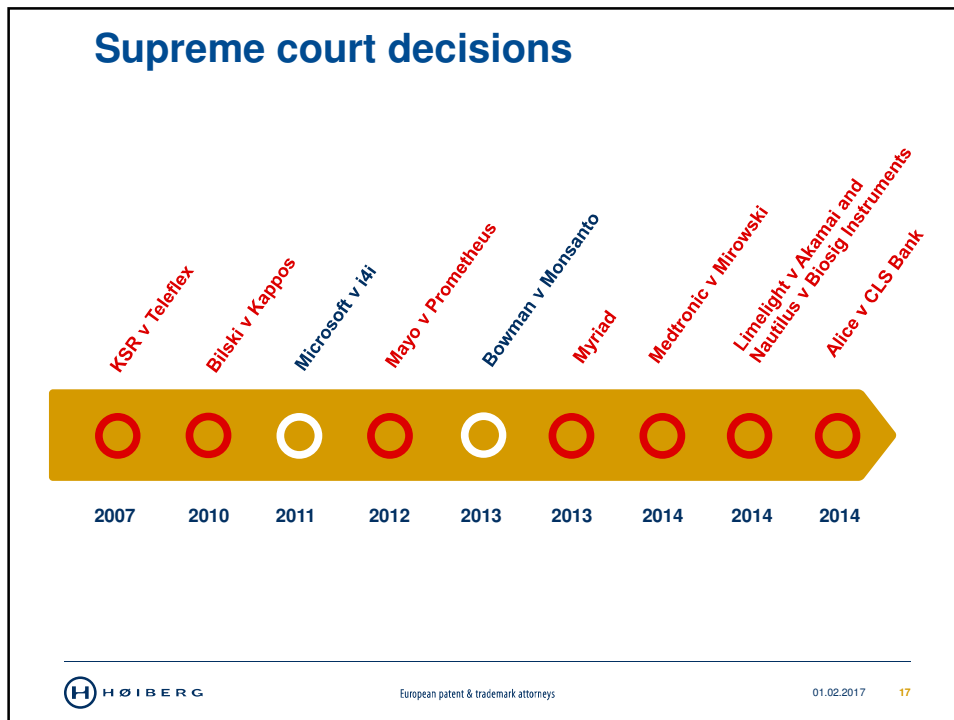
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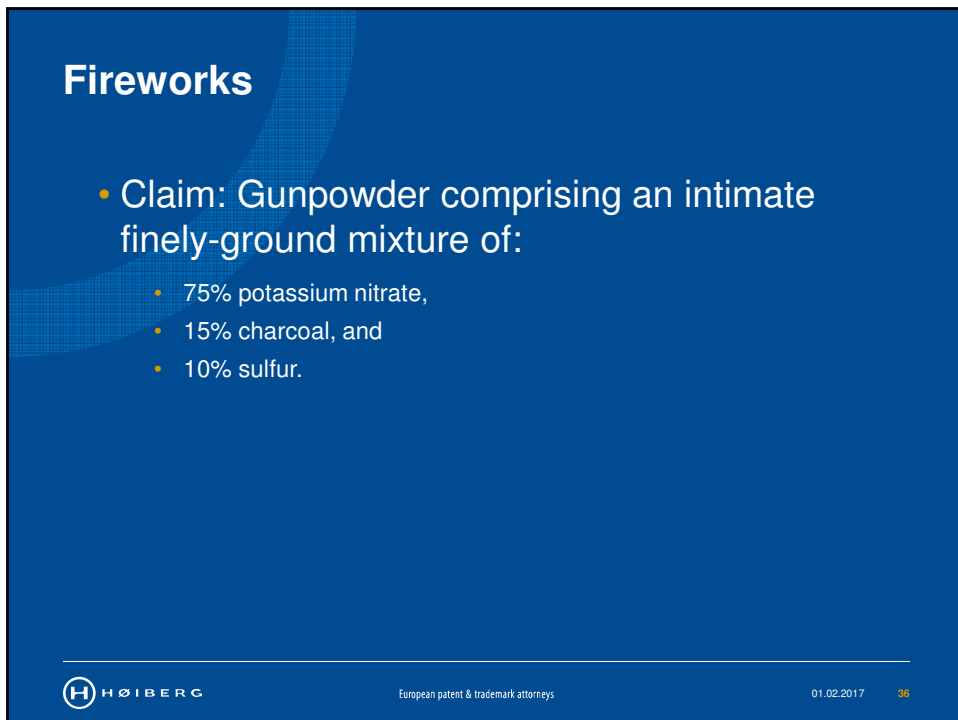
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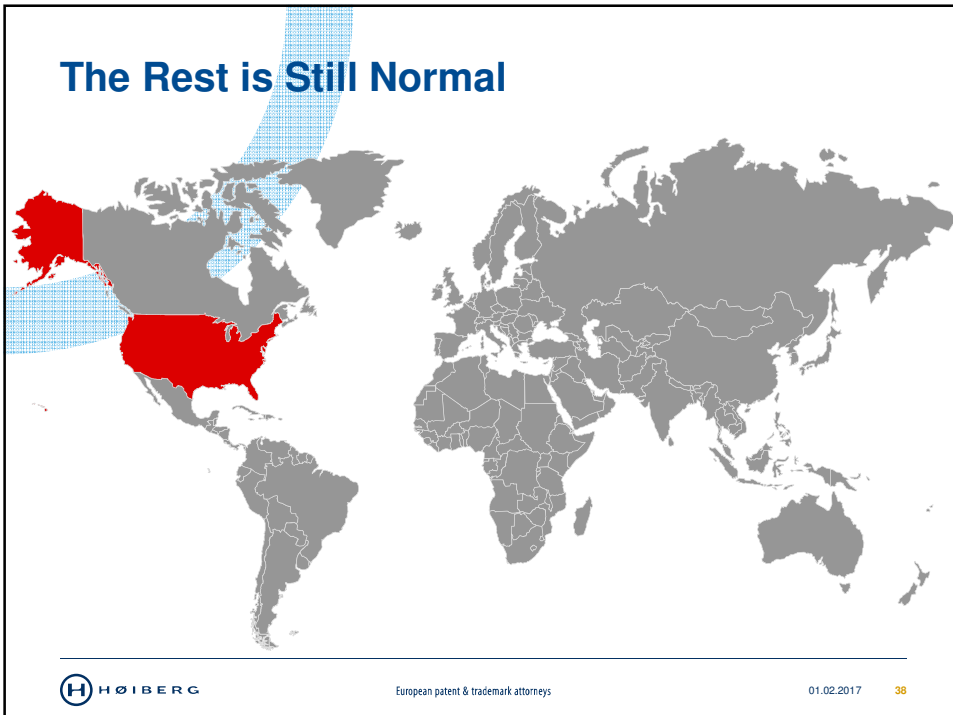
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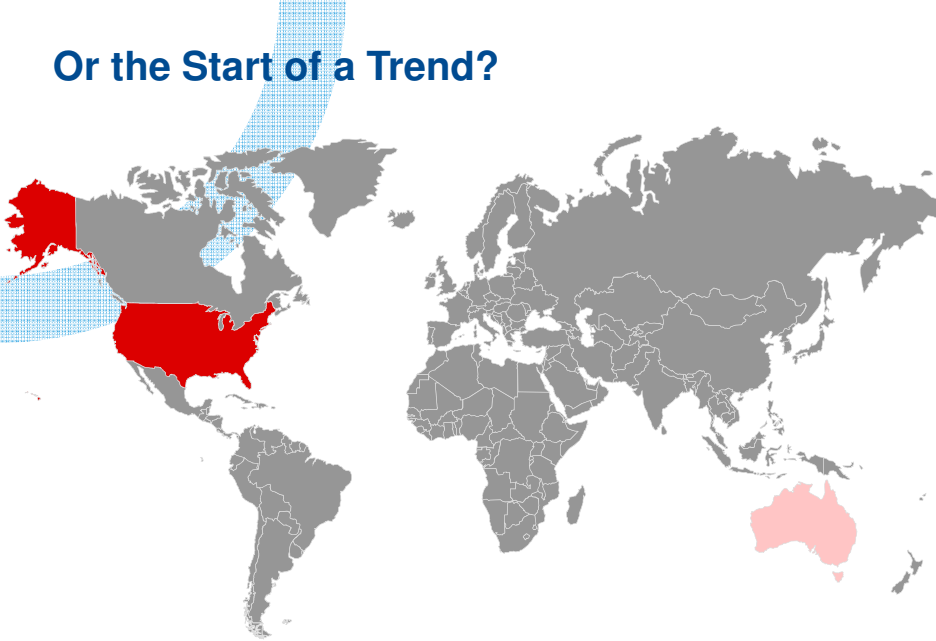
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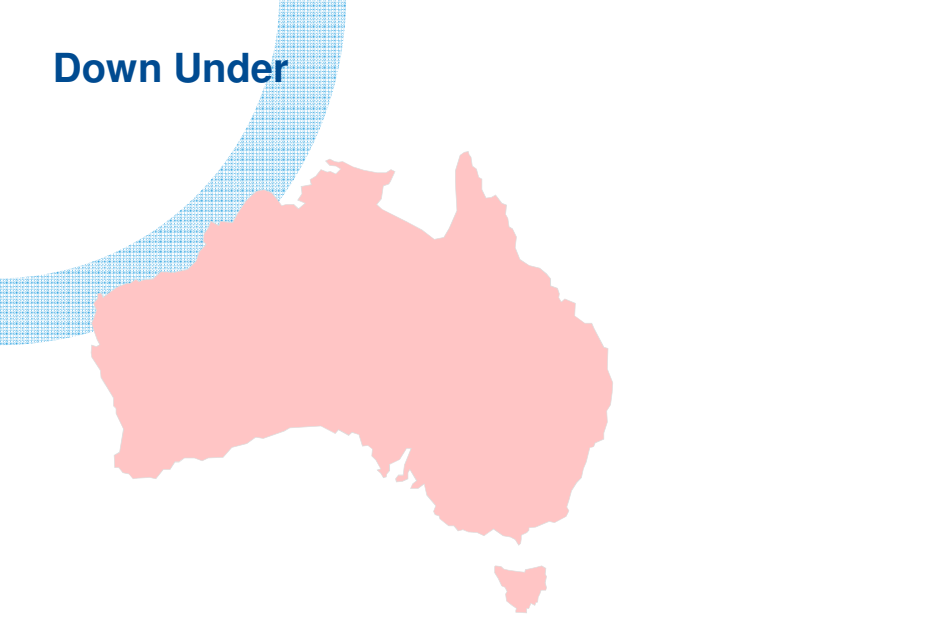
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Diagnostics


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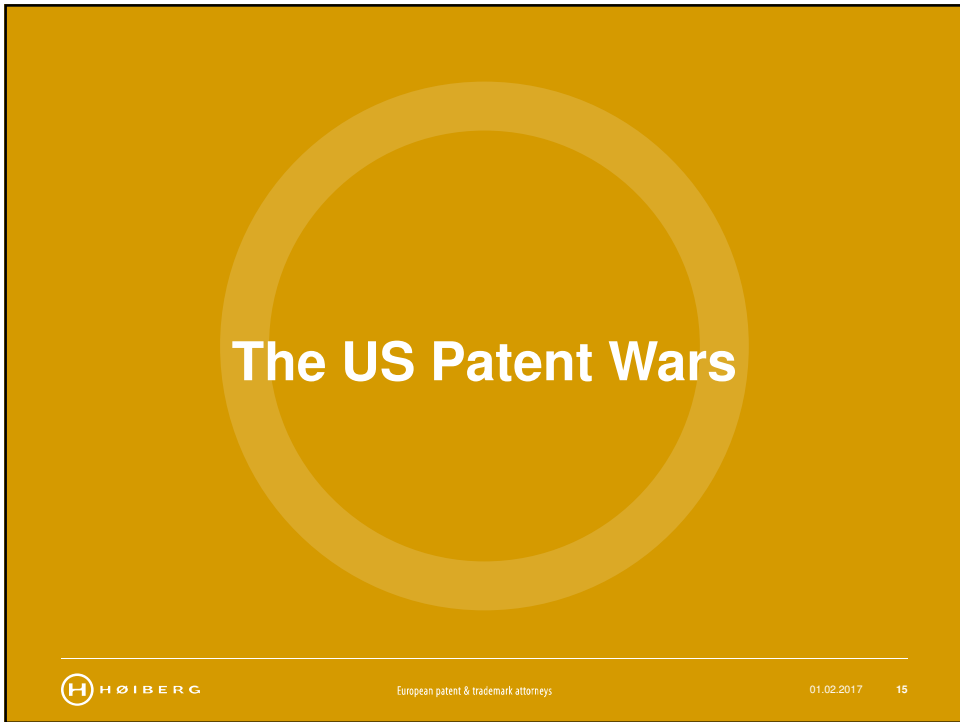
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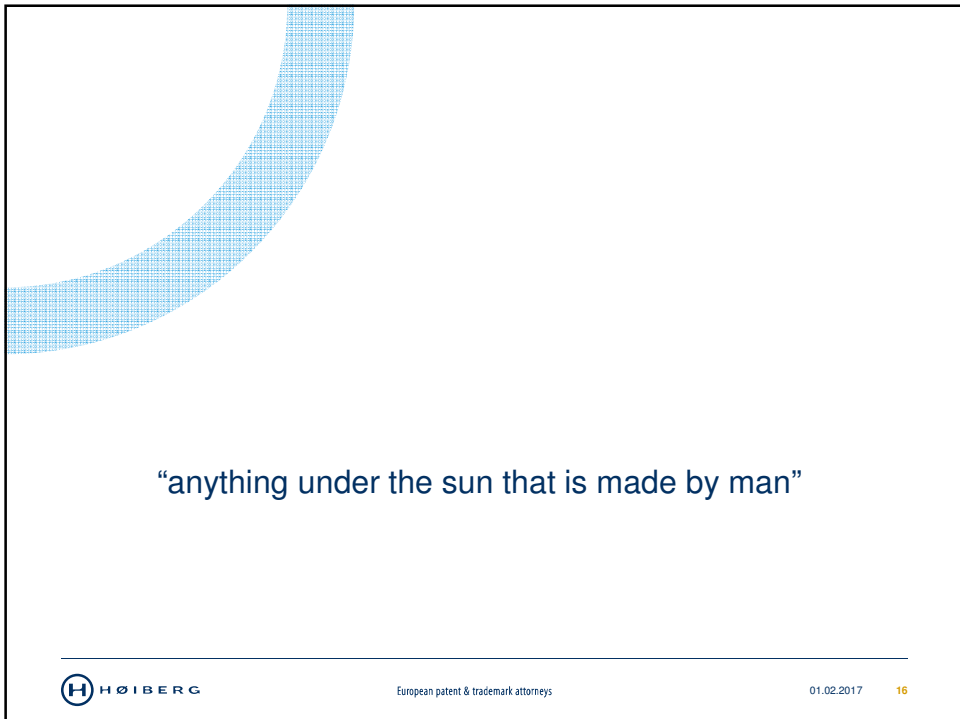
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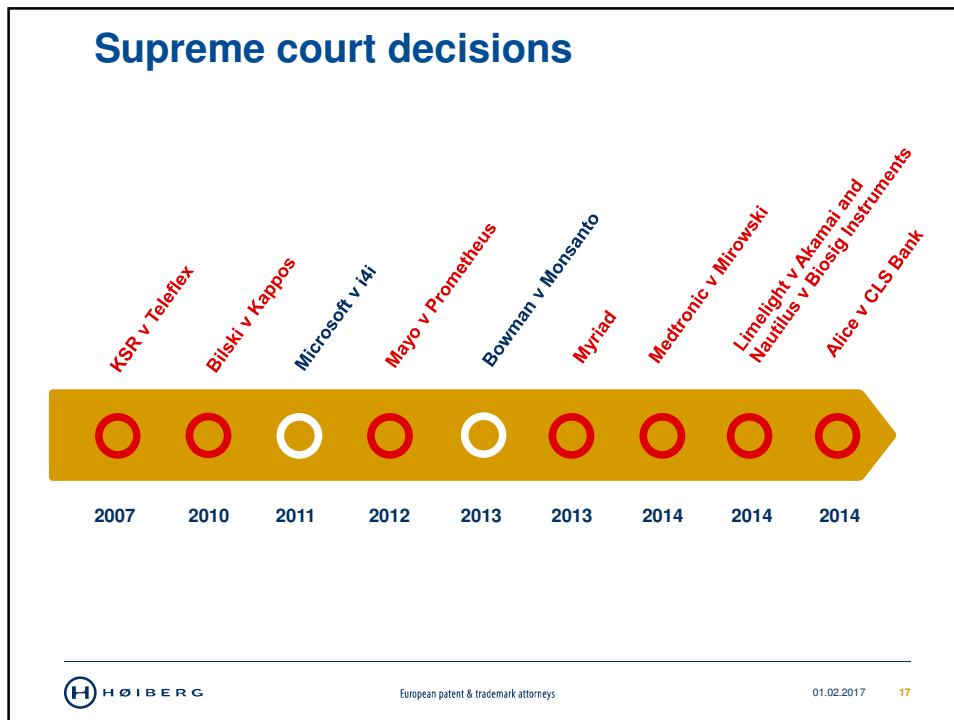
The US Patent Wars

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“anything under the sun that is made by man”

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- Recombinant proteins
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Amazonic acid background

Amazonian cherry tree grows wild in Amazonas

It's leaves contain a substance that has anti-cancer effects

Nobody has succeeded in isolating the compound

Amazonic acid background

Applicant has isolated amazonic acid

Has demonstrated effect in treatment of breast and colon cancer

Has created deoxy amazonic acid, with same activity as amazonic.

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- Claim 1: Purified amazonic acid
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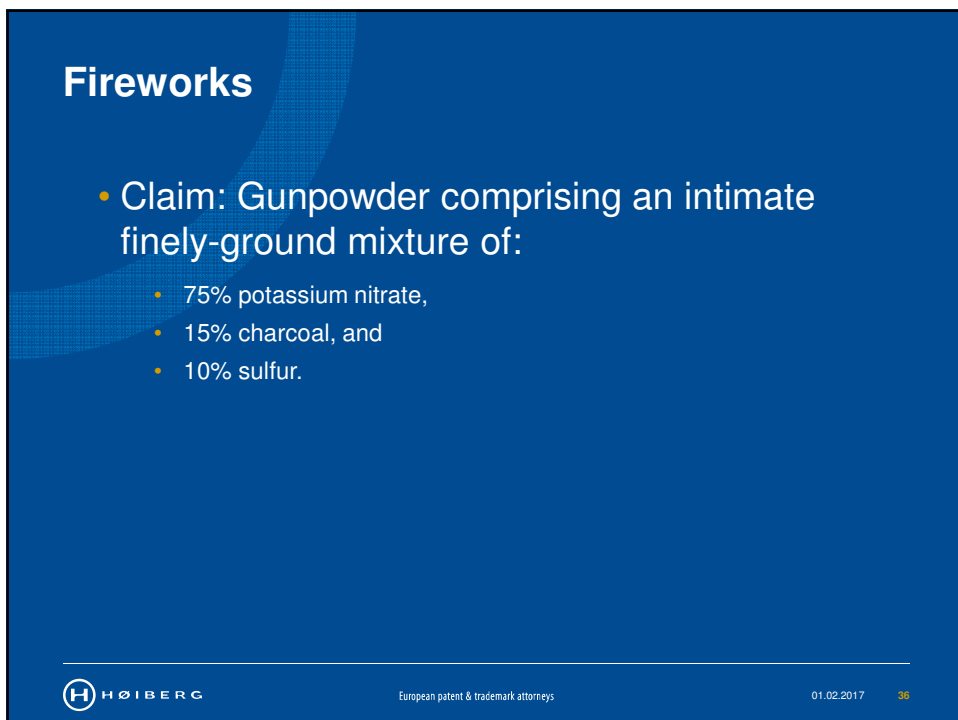


Gunpowder

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- Claim: Gunpowder comprising an intimate finely-ground mixture of:
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European patent & trademark attorneys

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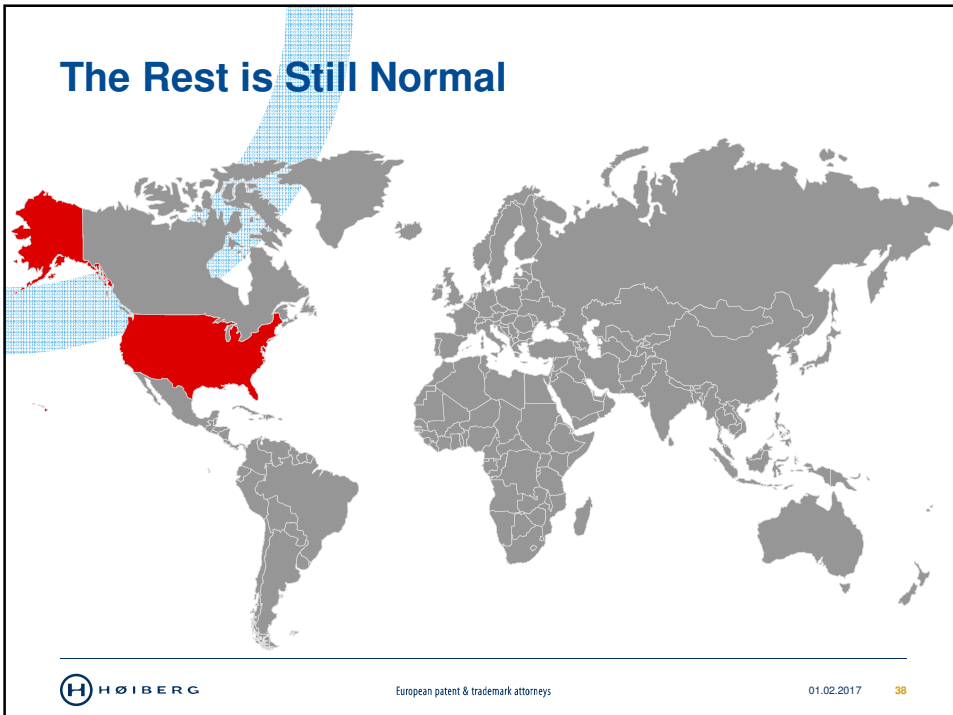
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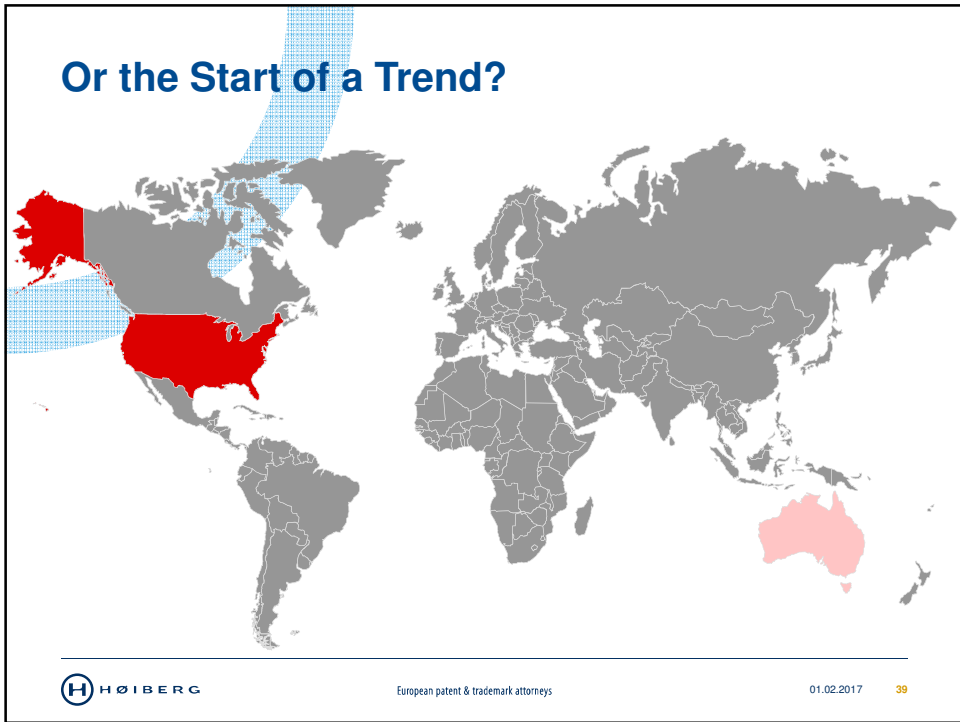
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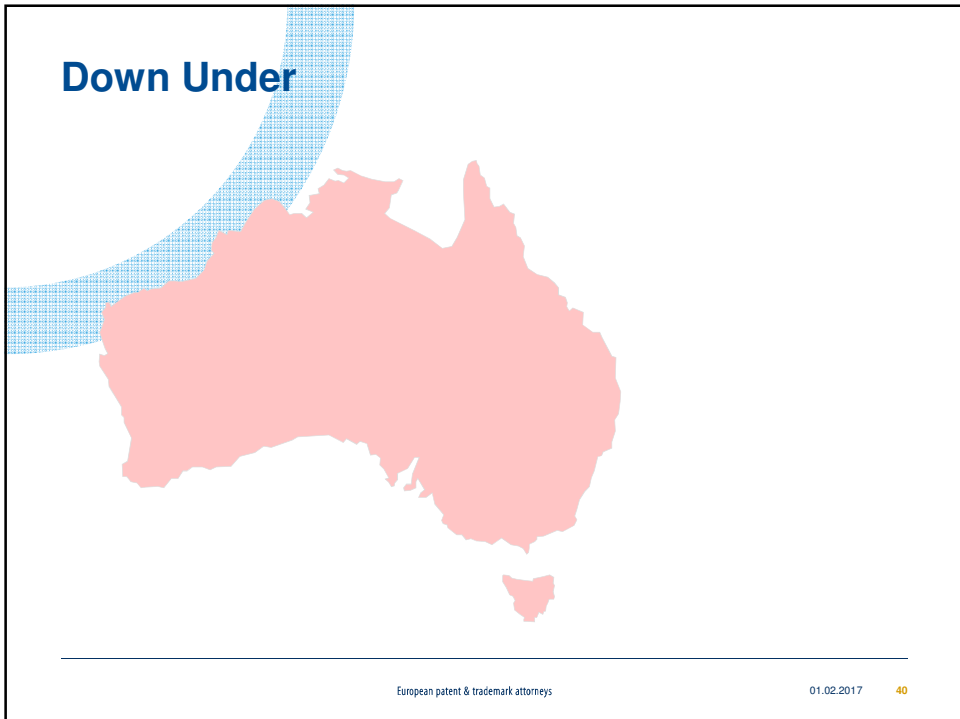
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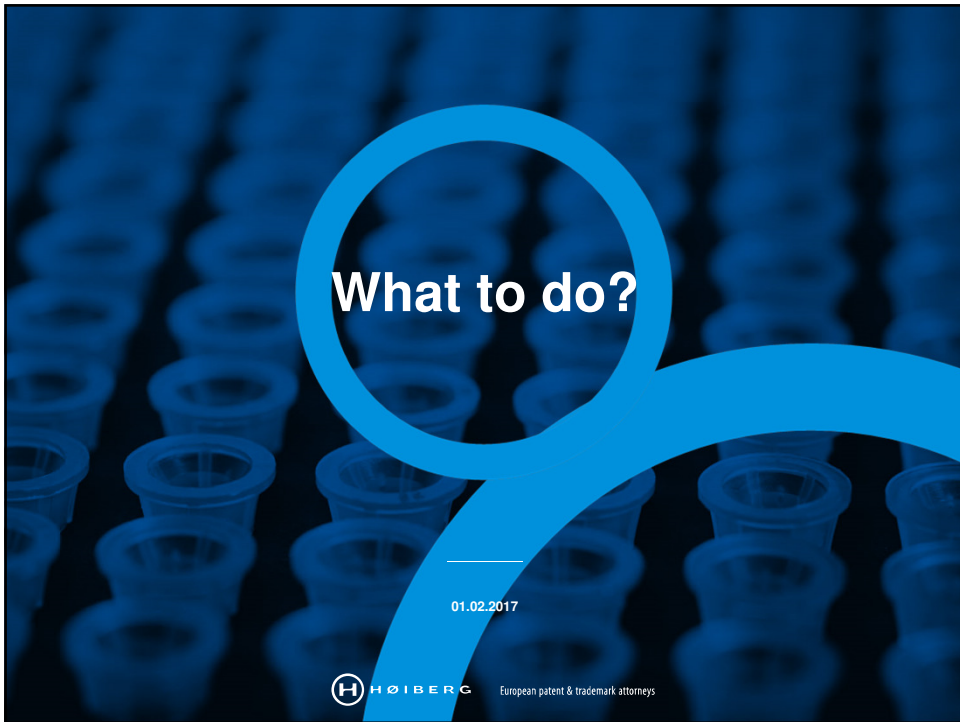
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Recent Decision from AU High Court


- Myriad Genetic's Australian patent on BRCA1 and BRCA2 mutations.
- Claims to isolated DNA: not patentable
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- Diagnostic methods: patentable

Guidance from AU Patent Office

- Proteins and peptides are patentable
- Isolated small molecules (amazonic acid) are patentable
- Diagnostic methods are patentable
- Methods of treatment are patentable



Diagnostics


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Diagnostics

Focus on new and patentable analytical methods

Measure the marker using MS, HPLC or similar "high tech"

Recite all steps of analytical method (e.g. PCR, Elisa)

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Diagnosis

Tie the diagnostic method to treatment, follow-on diagnostics

e.g. add a method of treatment step at the end (if tested positive for condition X, treat with drug Y)

Argue that the additional steps are not routine and conventional. If the claim is non-obvious, it should be patentable.

Compound patents

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Add synthesis claims – recombinant or synthetic

Add mutant/derivative/conjugate claims

Do not look for mutants/derivatives in nature

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- Business methods
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- No patents on plants, seeds, or animals
- No patents on drug formulations
- No patents on salts
- No patents on new use of known compound
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Exceptions to Patentability

What cannot be done

Jens Viktor Nørgaard
01.02.2017

 HØIBERG European patent & trademark attorneys

Speaker / CV



Jens Viktor Nørgaard

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Partner, European Patent Attorney, PhD,
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jvn@hoiberg.com

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Agenda

Stem cells
Plant varieties
Products of nature
Laws of nature
Abstract ideas

Why Exceptions



- Ethics, morale
- Non-technical
- Alternative types of protection
- Courts' interpretation of the law
- Public/lobbyist pressure

East meets West

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- Board of Appeal of EPO, German Courts and European Court of Justice have decided that an embryo encompasses a fertilised human egg, i.e. a stem cell
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European patent & trademark attorneys
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Plant Varieties - Background

New plant varieties can be Protected (UPOV; CPVO)

European exception

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European patent & trademark attorneys
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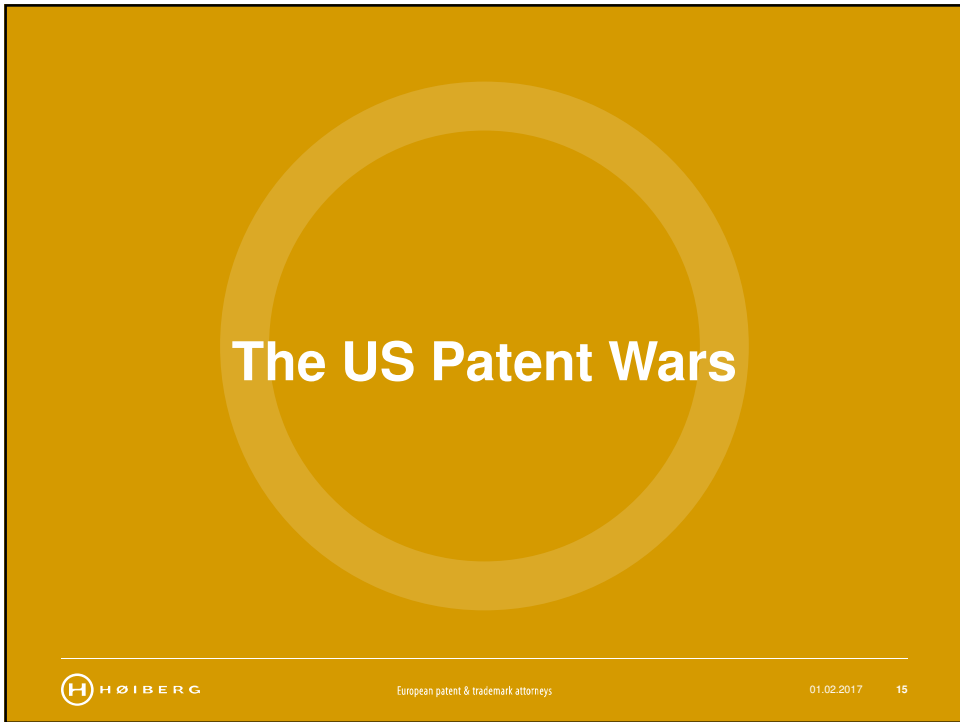
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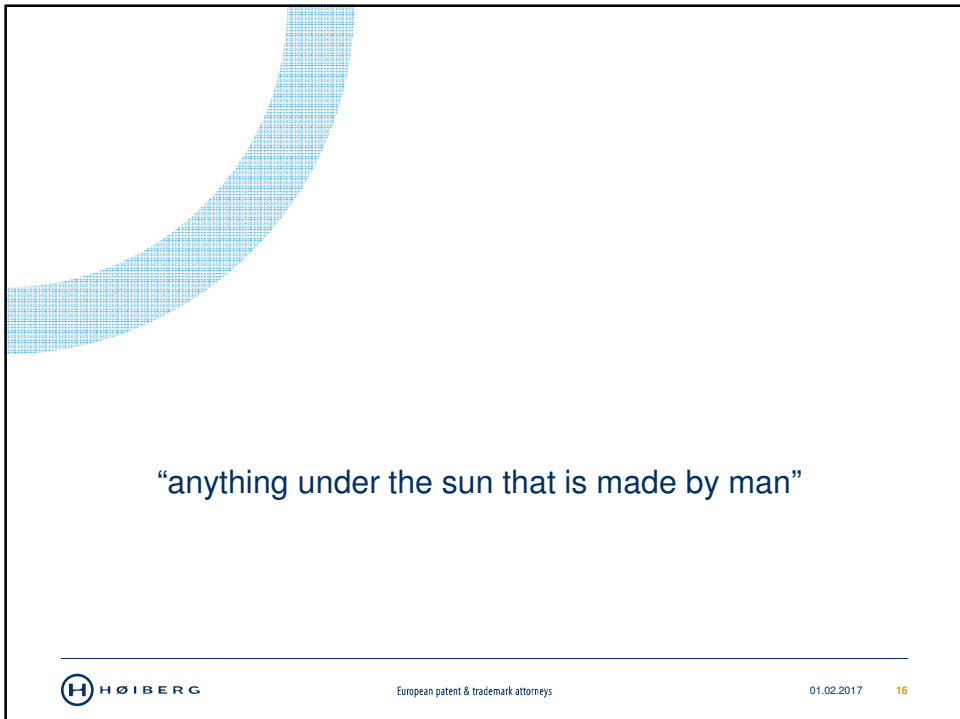
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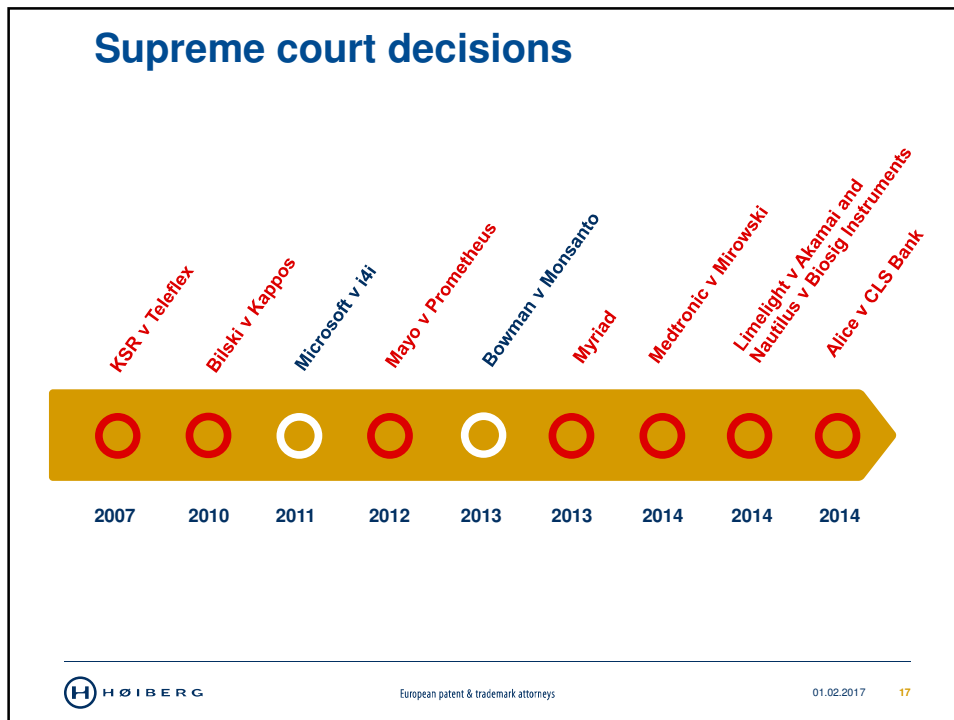
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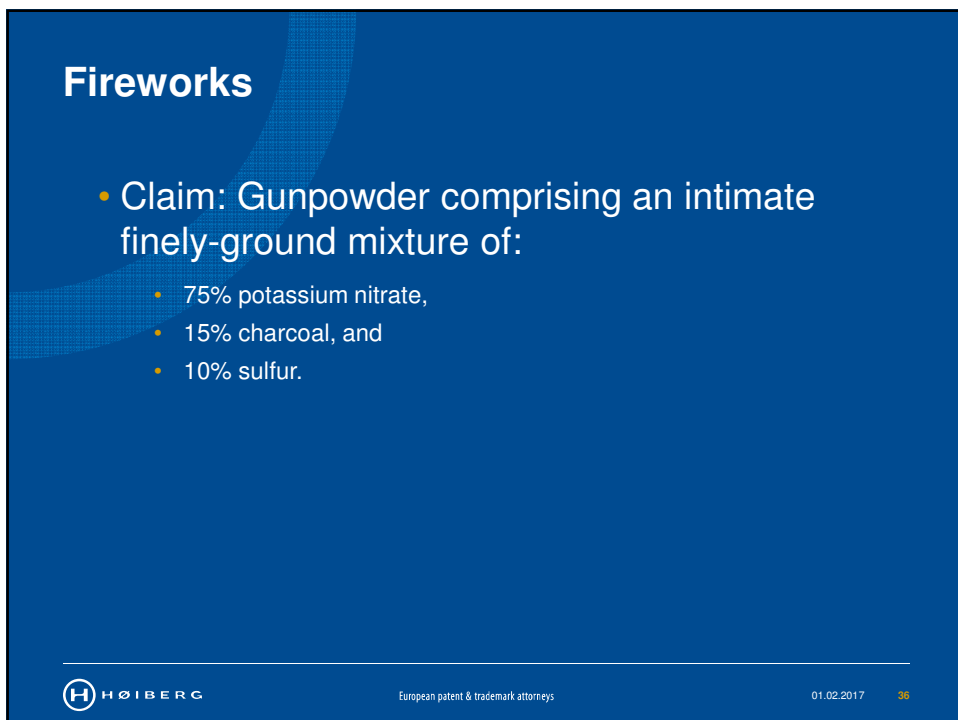


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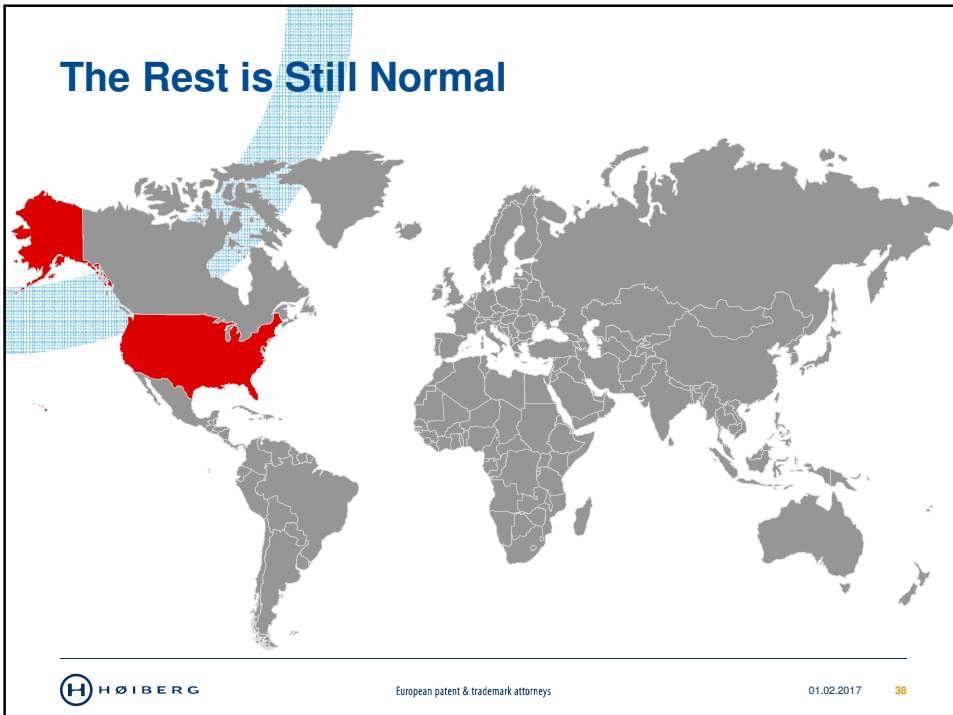
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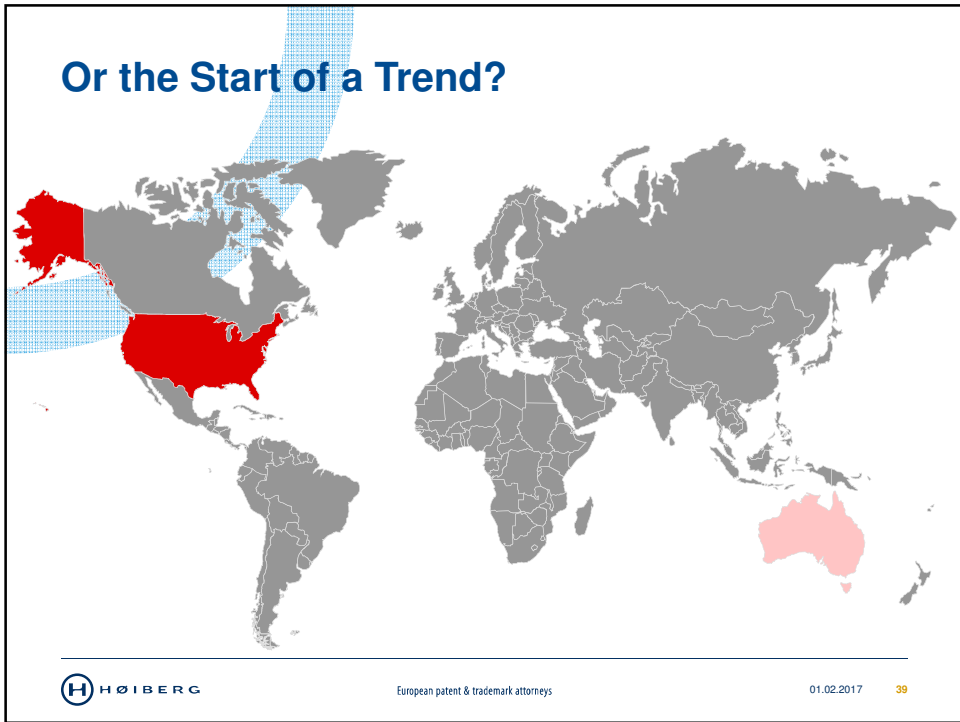
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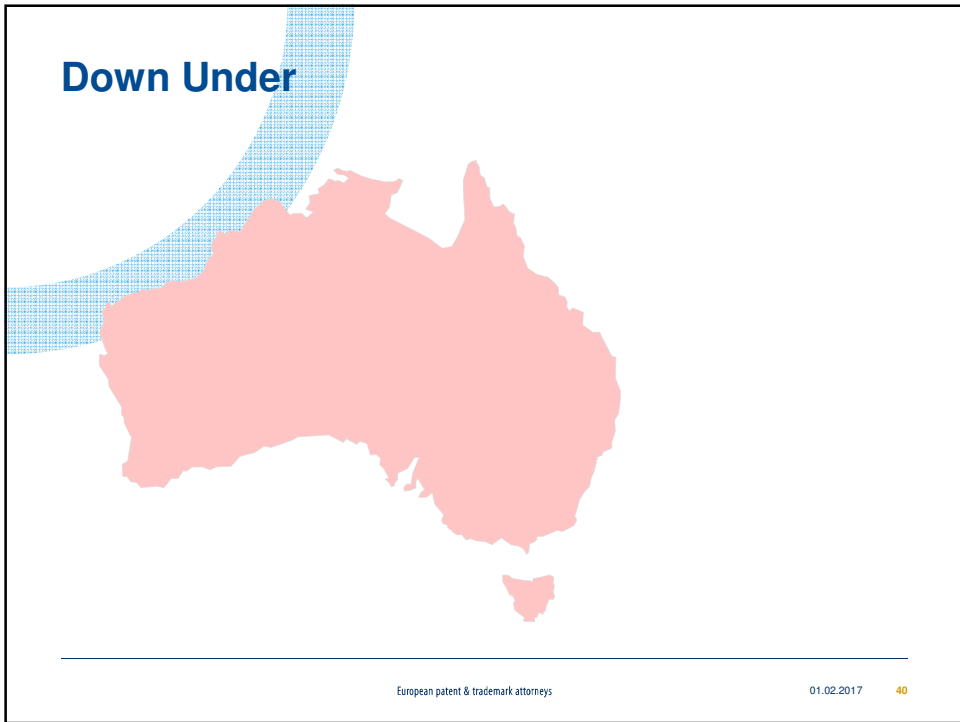
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European patent & trademark attorneys

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Speaker / CV



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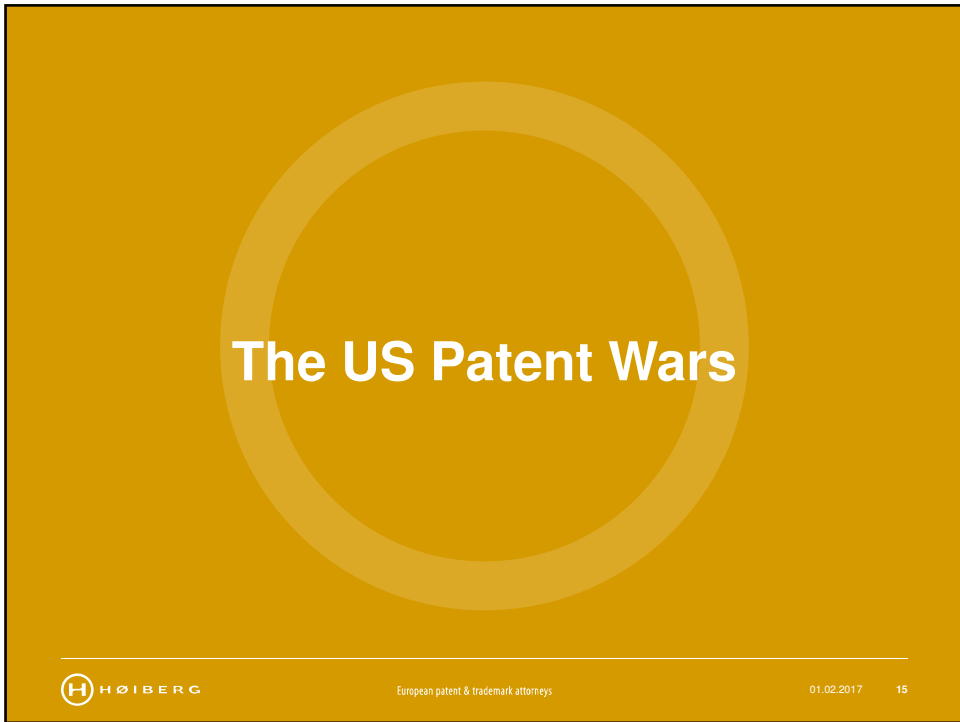
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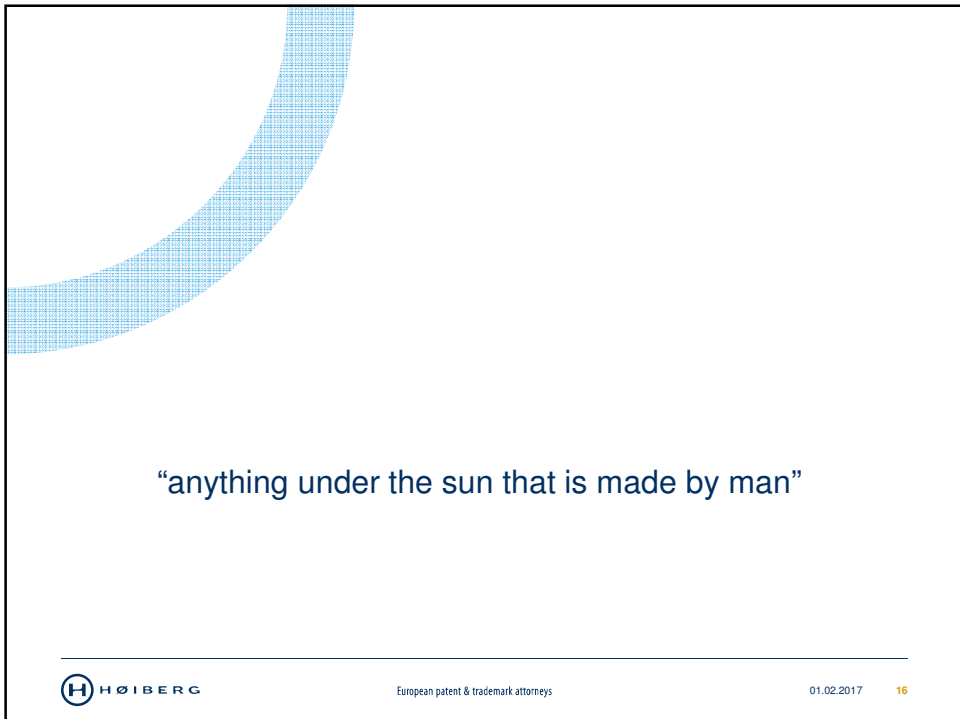
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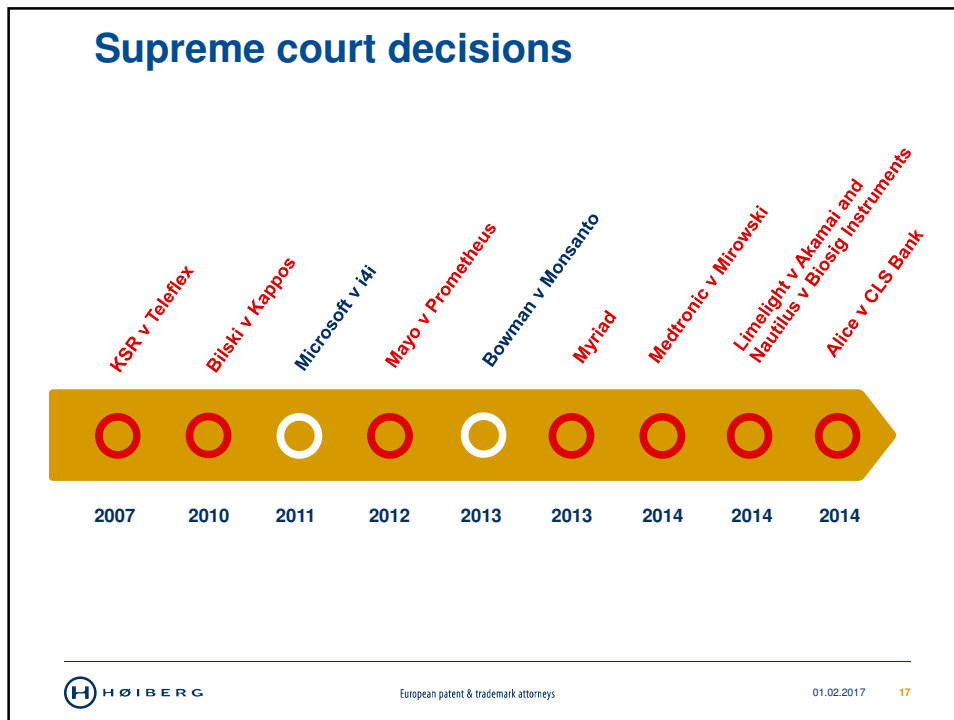
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Amazonic acid background

Amazonian cherry tree grows wild in Amazonas

It's leaves contain a substance that has anti-cancer effects

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- Claim 1: Purified amazonic acid
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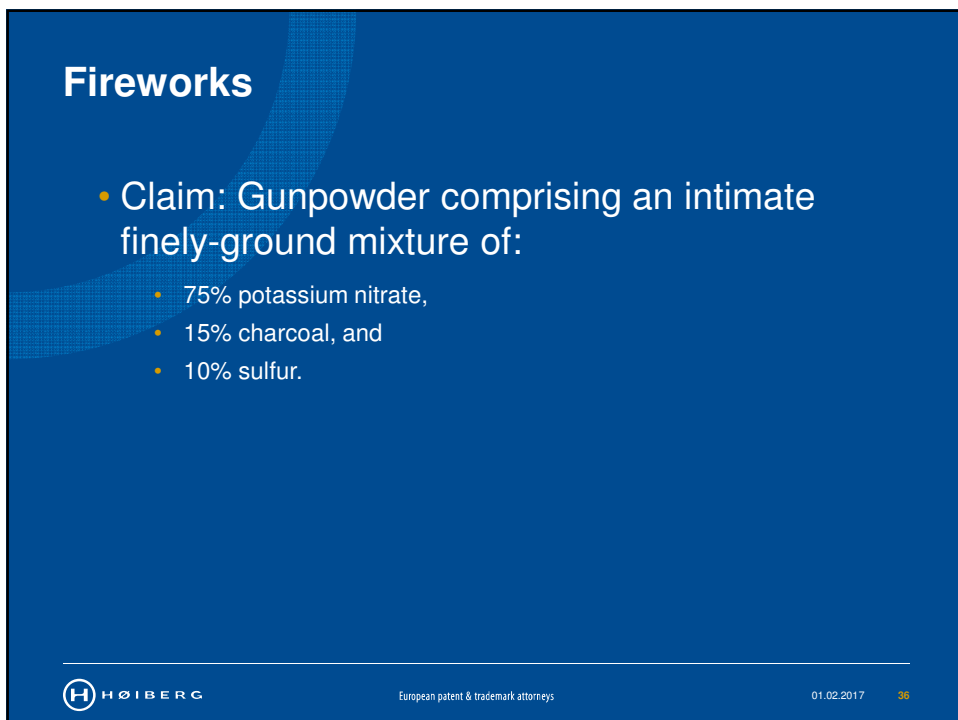
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Gunpowder

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Fireworks

- Claim: Gunpowder comprising an intimate finely-ground mixture of:
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 HØIBERG European patent & trademark attorneys 01.02.2017 96

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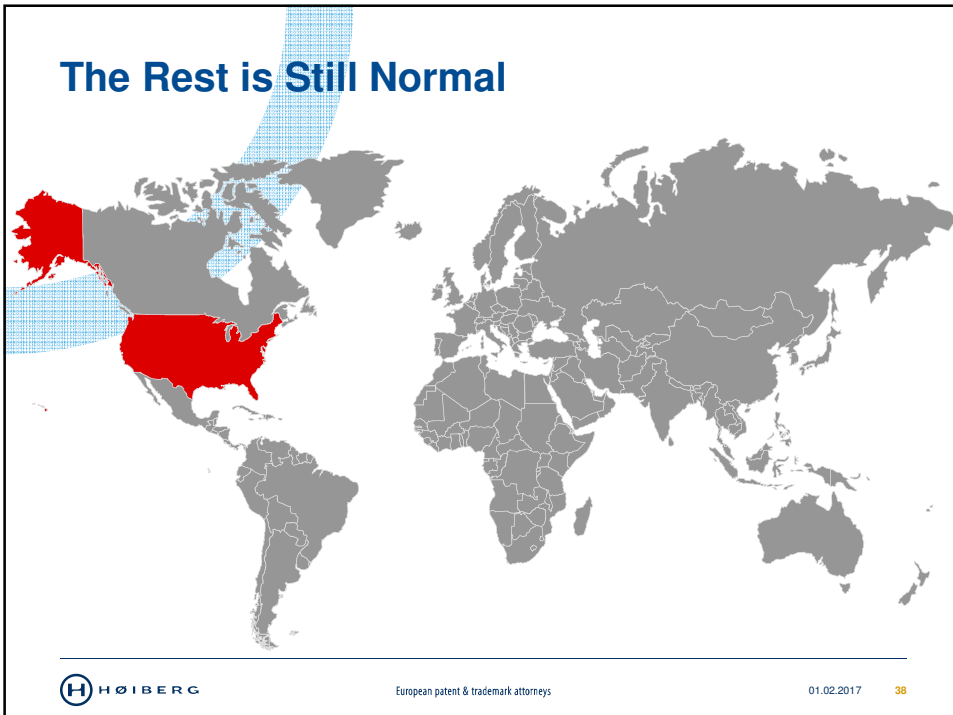
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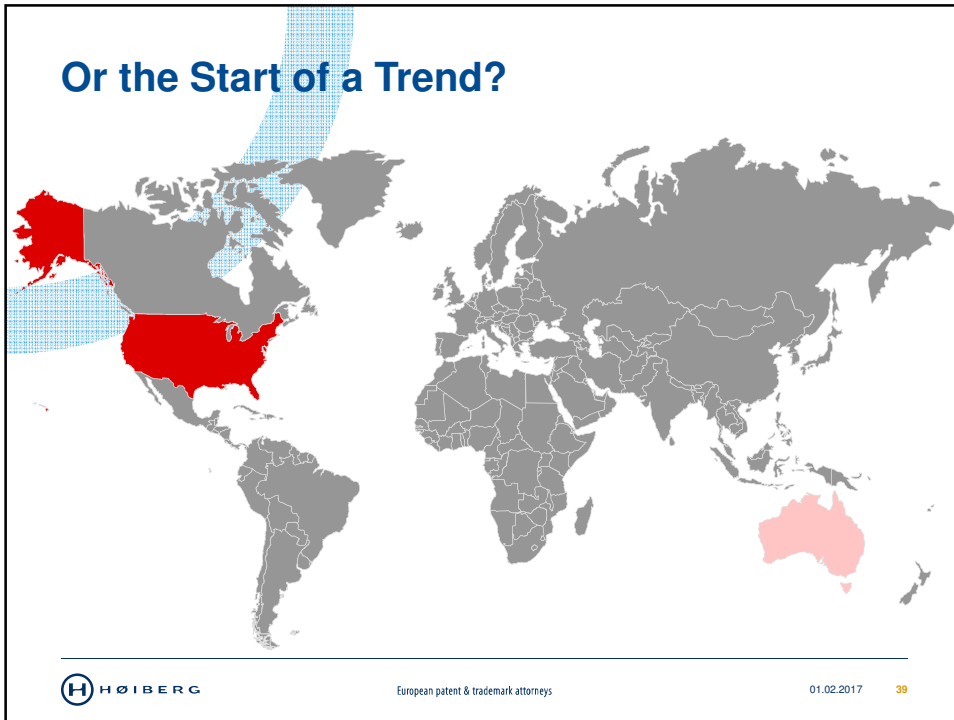
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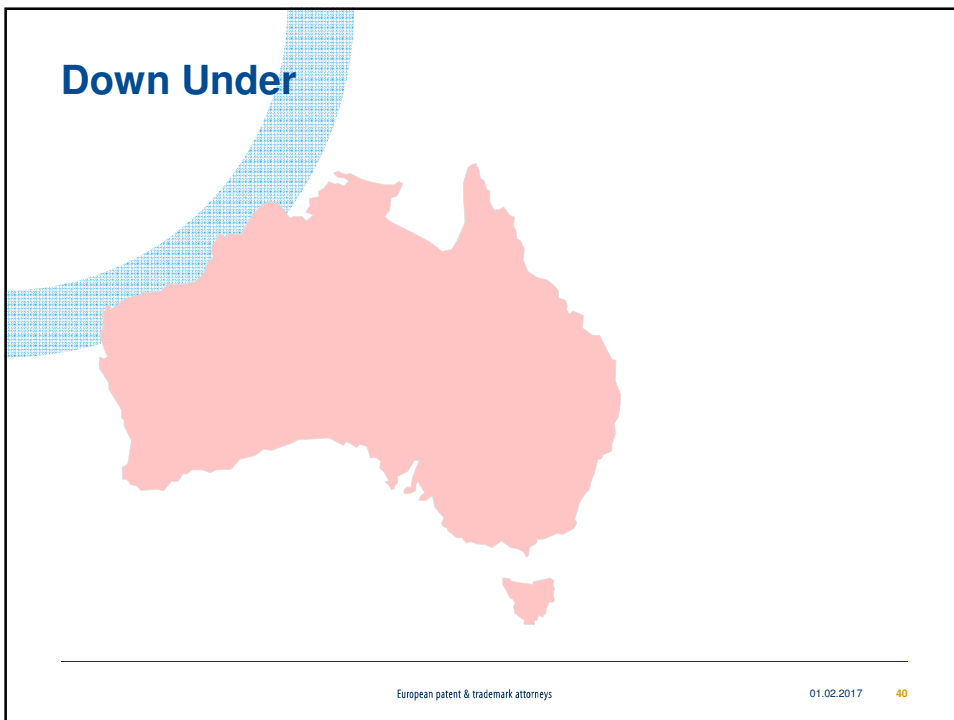
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Recent Decision from AU High Court


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Diagnostics


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Diagnostics

Focus on new and patentable analytical methods

Measure the marker using MS, HPLC or similar "high tech"

Recite all steps of analytical method (e.g. PCR, Elisa)

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Diagnosis

Tie the diagnostic method to treatment, follow-on diagnostics

e.g. add a method of treatment step at the end (if tested positive for condition X, treat with drug Y)

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Add mutant/derivative/conjugate claims

Do not look for mutants/derivatives in nature

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- Computer programs "as such"

India

- No patents on plants, seeds, or animals
- No patents on drug formulations
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- No patents on new use of known compound
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**Thank you
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Exceptions to Patentability

What cannot be done

Jens Viktor Nørgaard
01.02.2017

 HØIBERG European patent & trademark attorneys

Speaker / CV



Jens Viktor Nørgaard

Head of Biotechnology & Plant sciences
Partner, European Patent Attorney, PhD,
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jvn@hoiberg.com

 HØIBERG European patent & trademark attorneys 01.02.2017

Agenda

Stem cells
Plant varieties
Products of nature
Laws of nature
Abstract ideas

Why Exceptions



- Ethics, morale
- Non-technical
- Alternative types of protection
- Courts' interpretation of the law
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East meets West

USA

Common law country

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- The law:
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Plant Varieties

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European patent & trademark attorneys
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Plant Varieties - Background

New plant varieties can be Protected (UPOV; CPVO)

European exception

Breeder's & farmer's privilege

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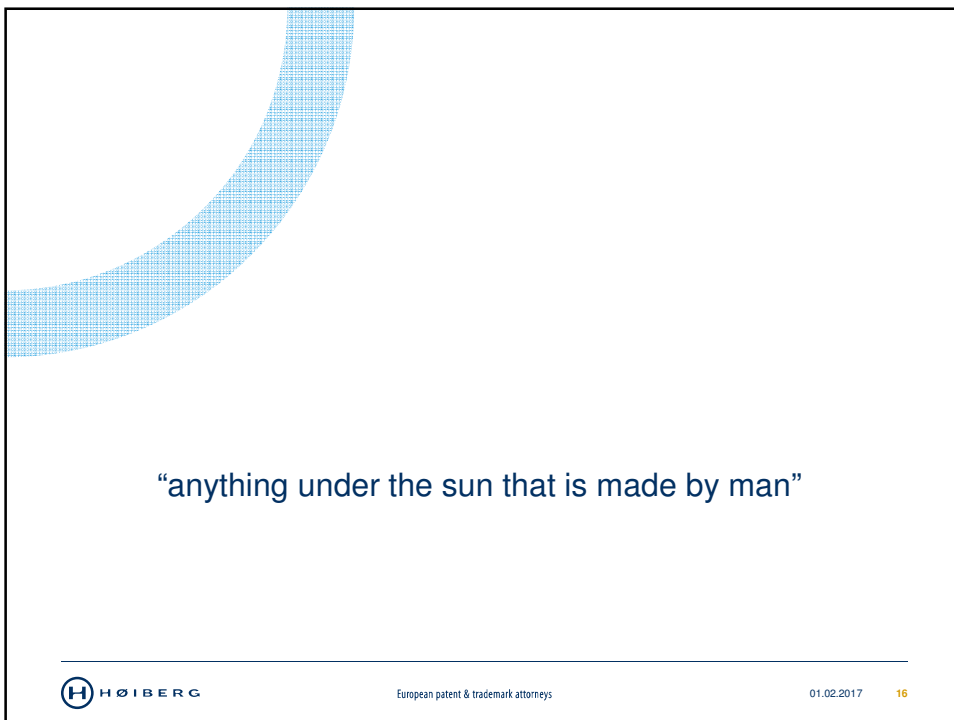
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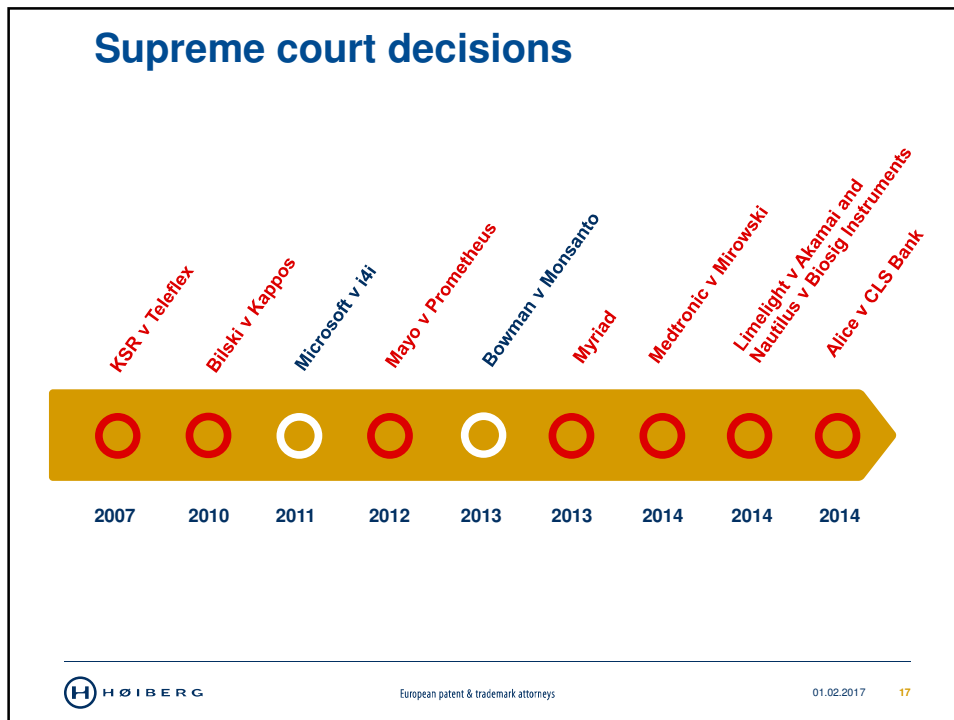
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 HØIBERG European patent & trademark attorneys 01.02.2017 16

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Patent eligible subject matter (§ 101):
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Mayo vs. Prometheus

- Prometheus Labs had rights to a series of US patents directed to a diagnostic method.
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 European patent & trademark attorneys
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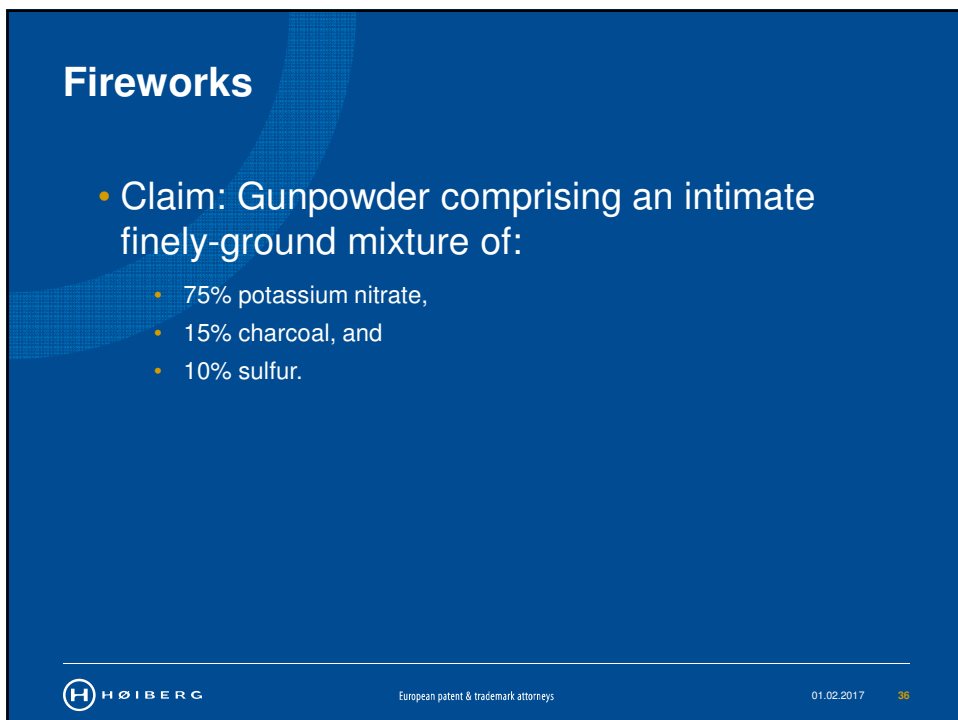
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Gunpowder

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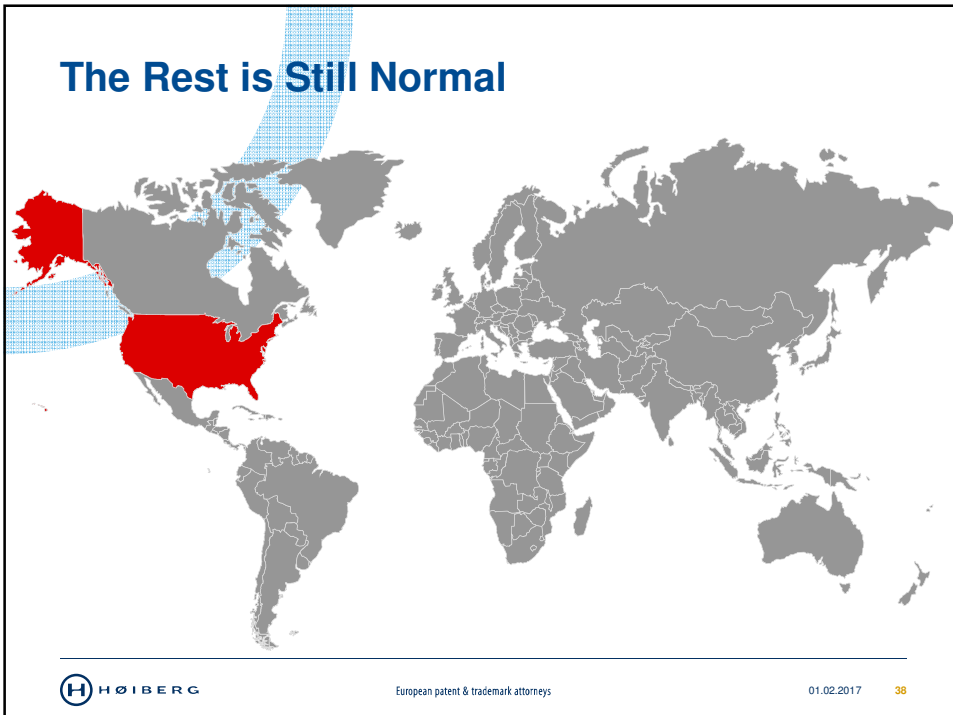
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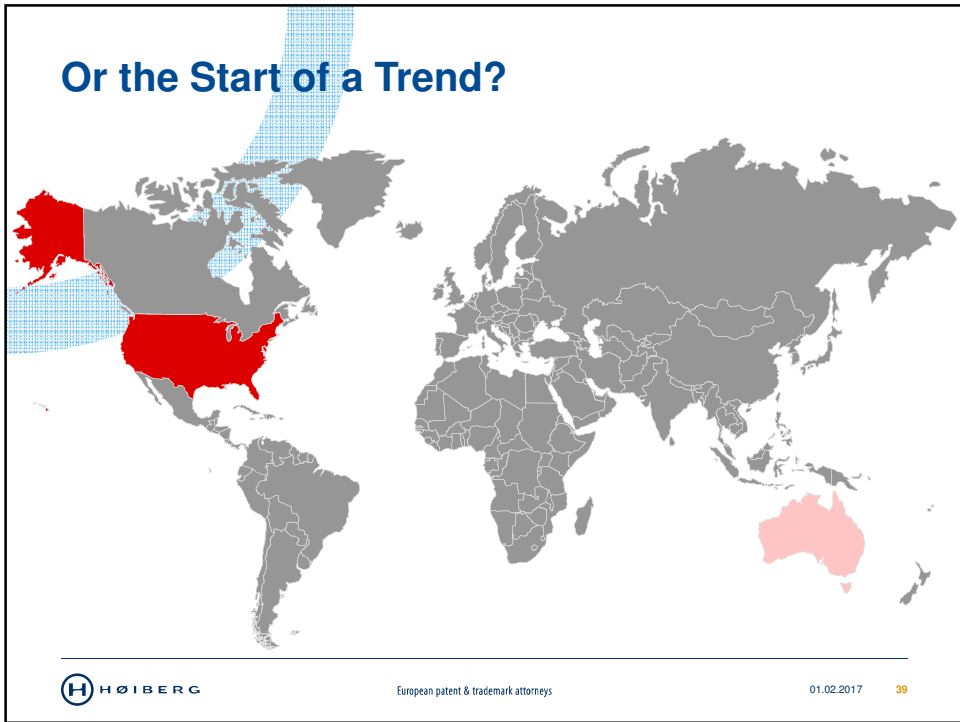
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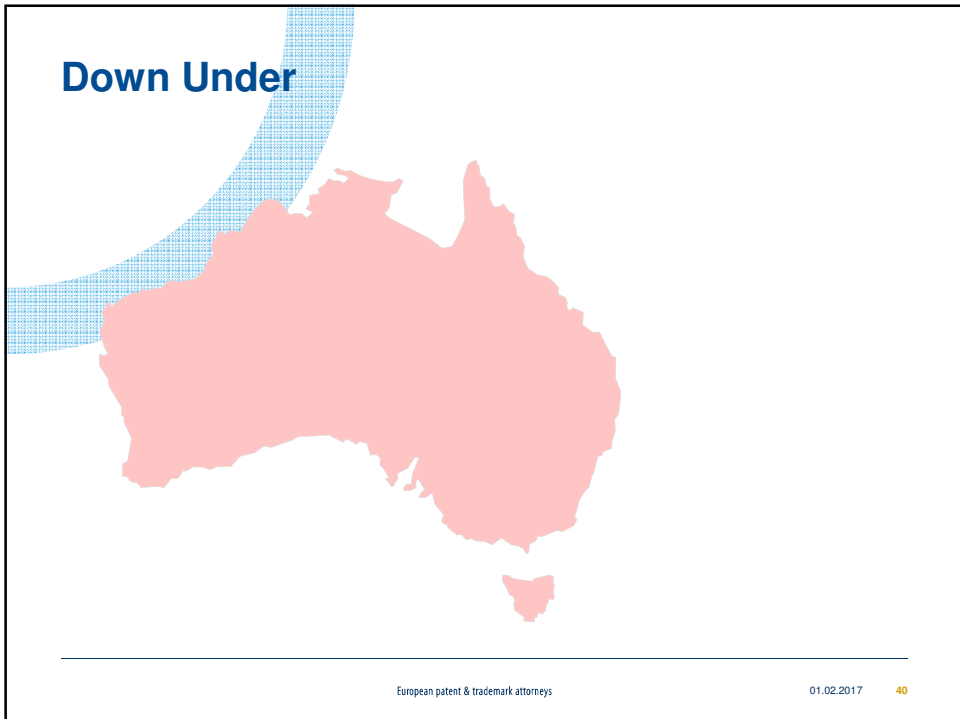
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European patent & trademark attorneys

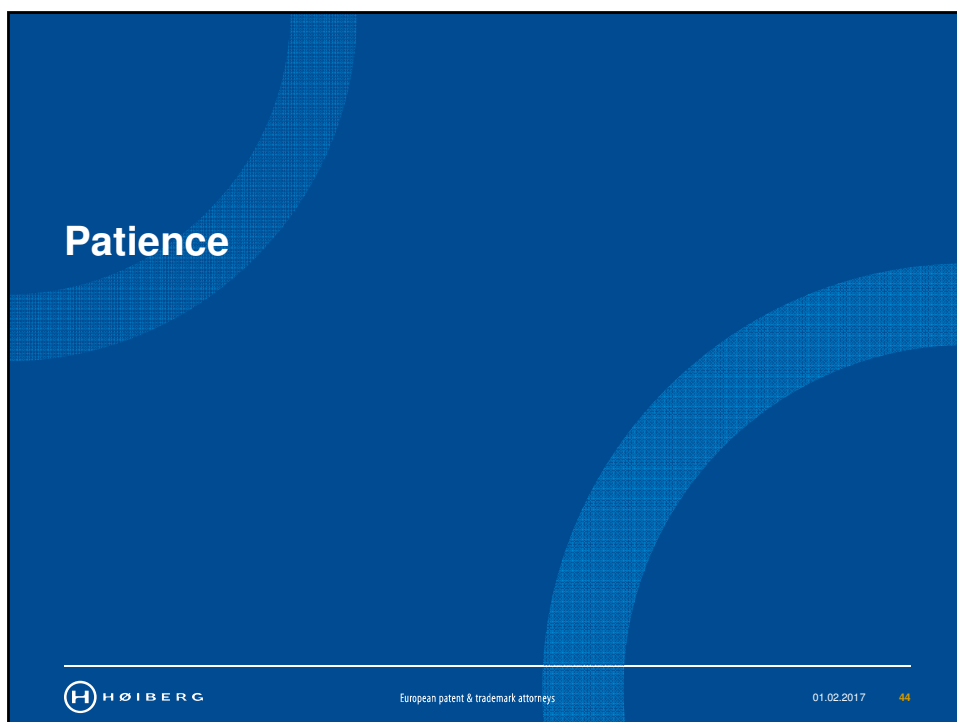
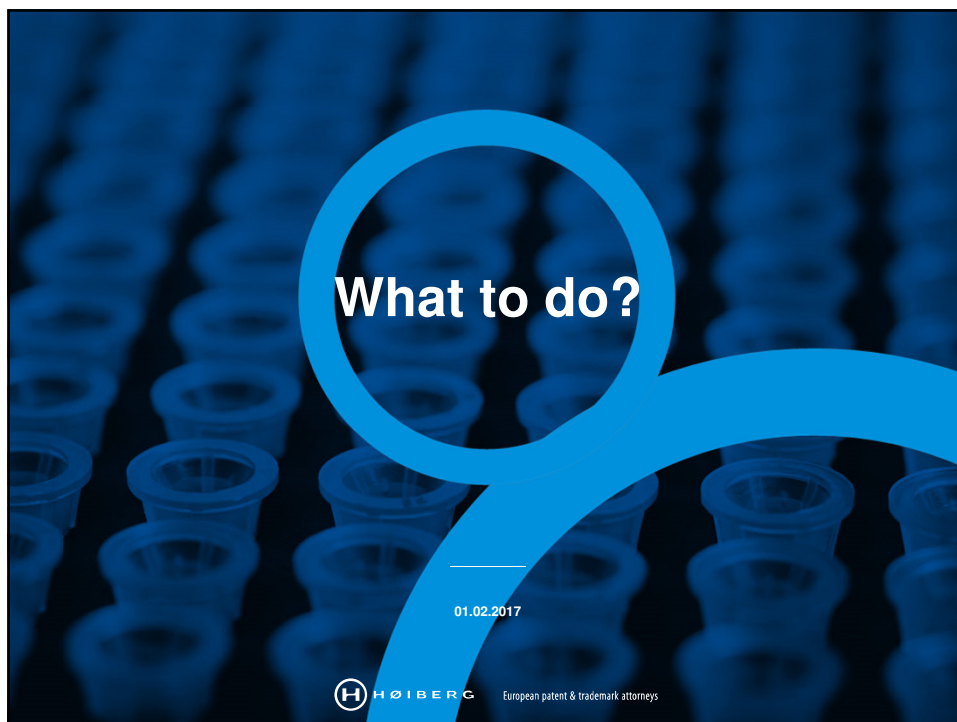
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Agenda


Stem cells
Plant varieties
Products of nature
Laws of nature
Abstract ideas

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Why Exceptions



- Ethics, morale
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European patent & trademark attorneys
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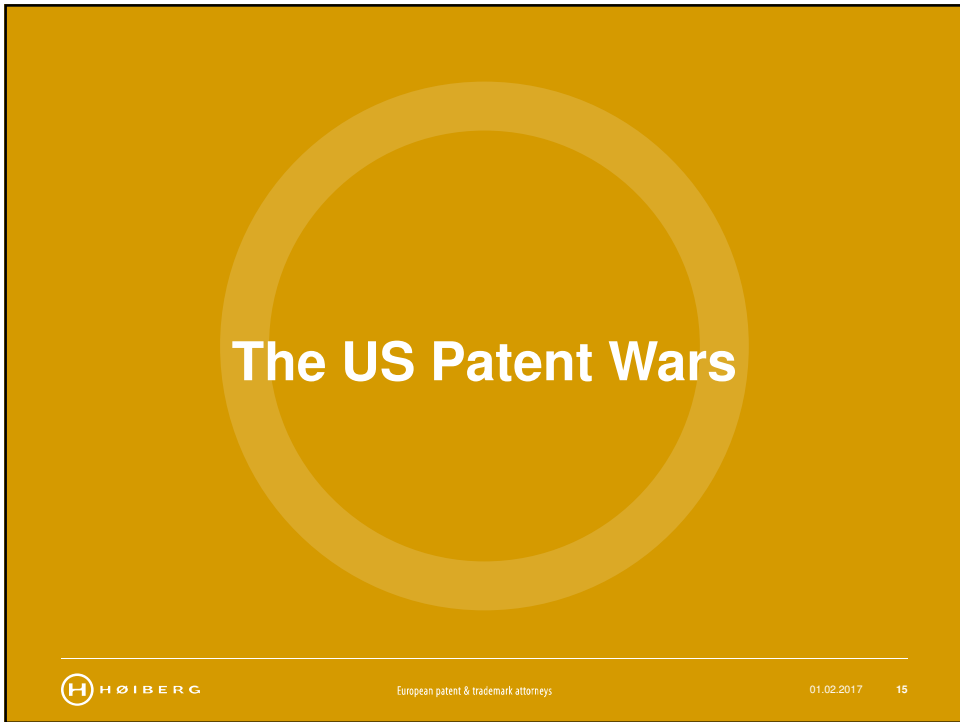
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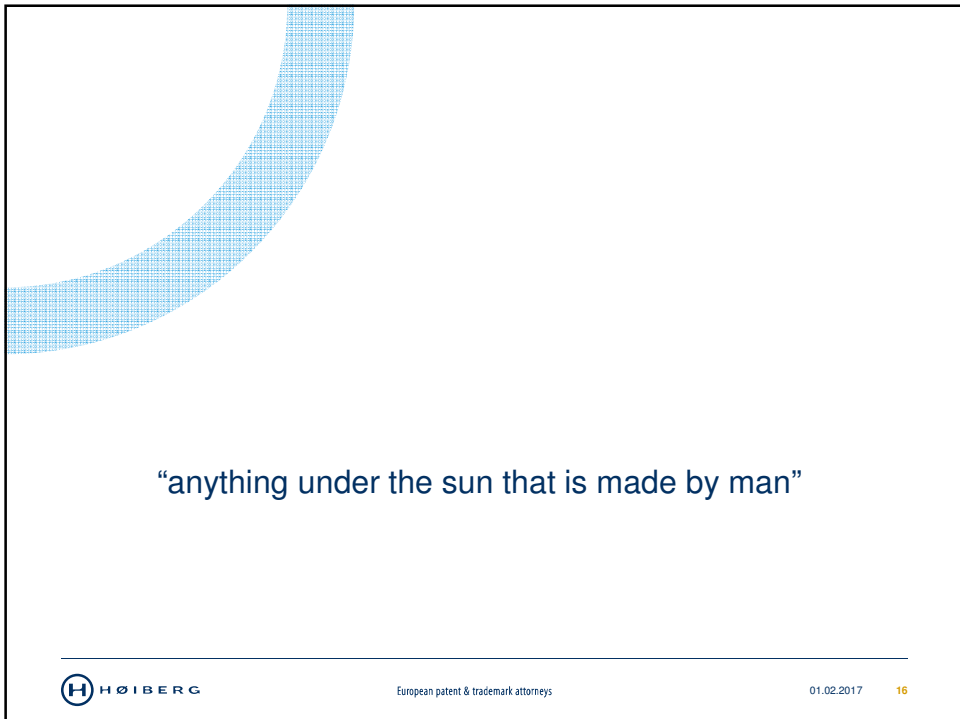
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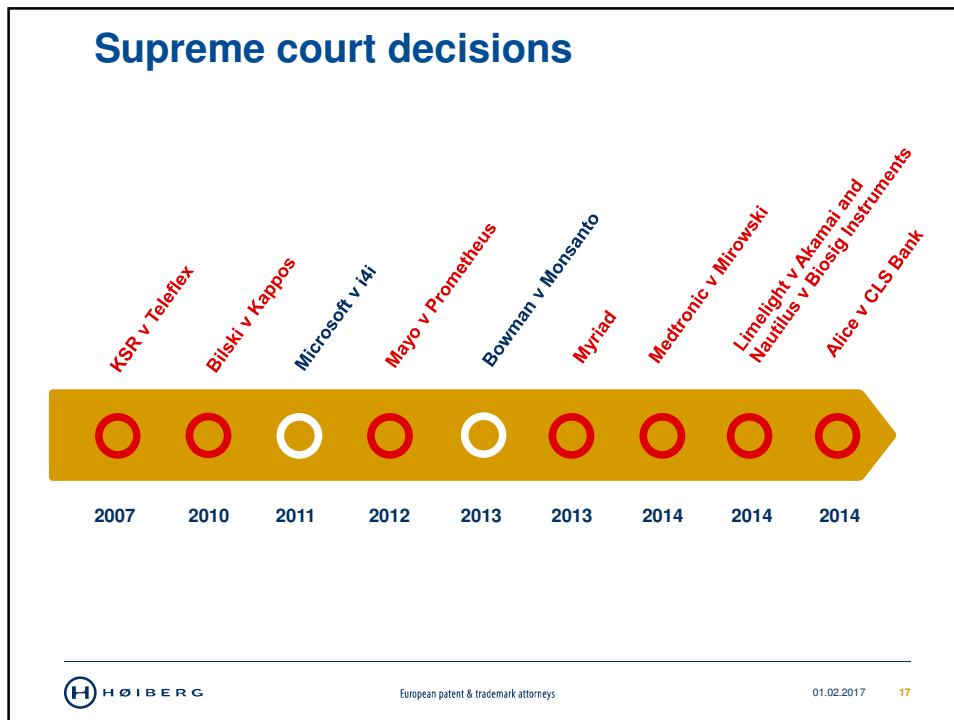
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 HØIBERG European patent & trademark attorneys 01.02.2017 22

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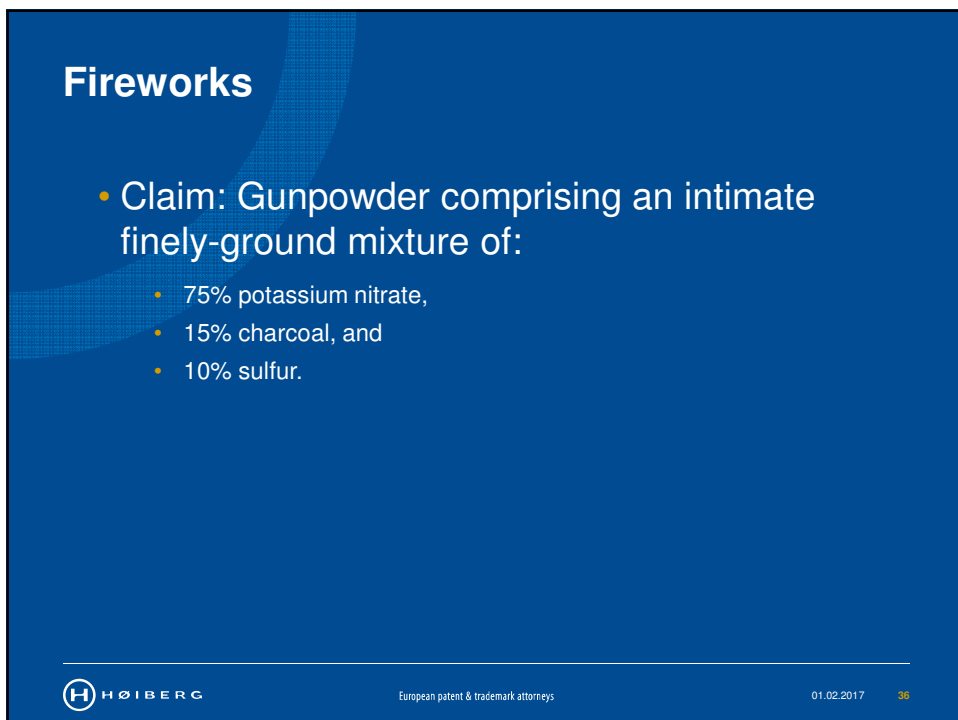


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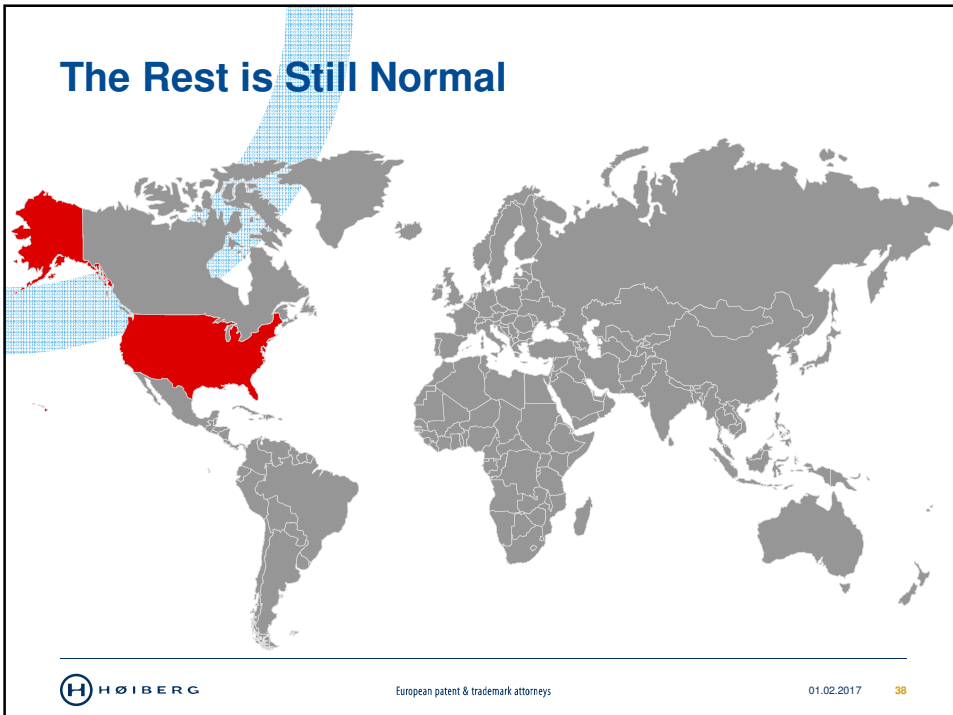
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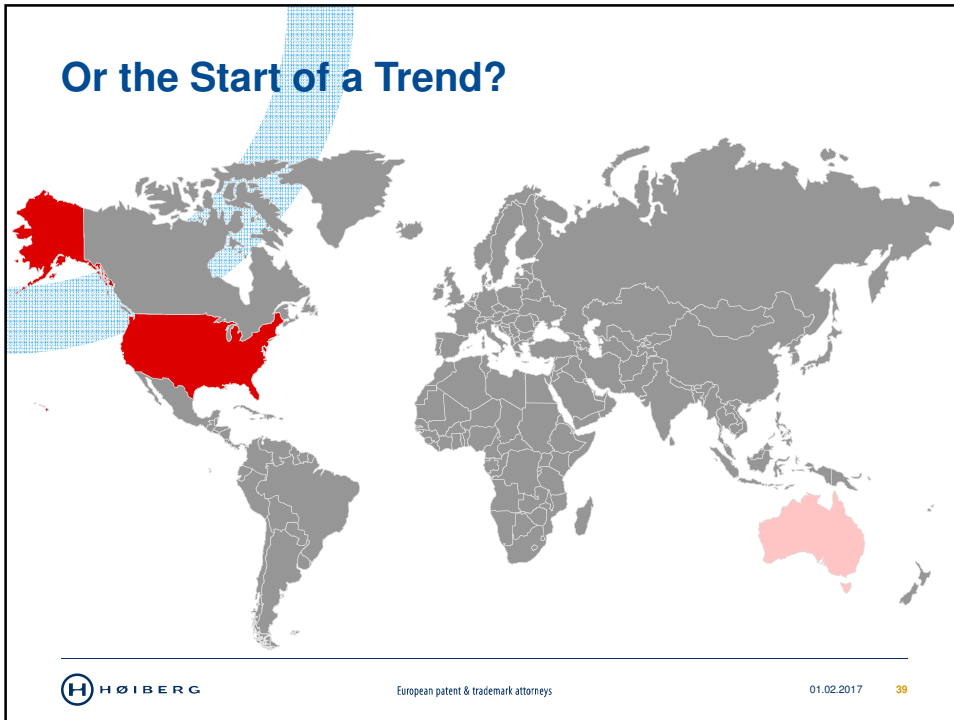
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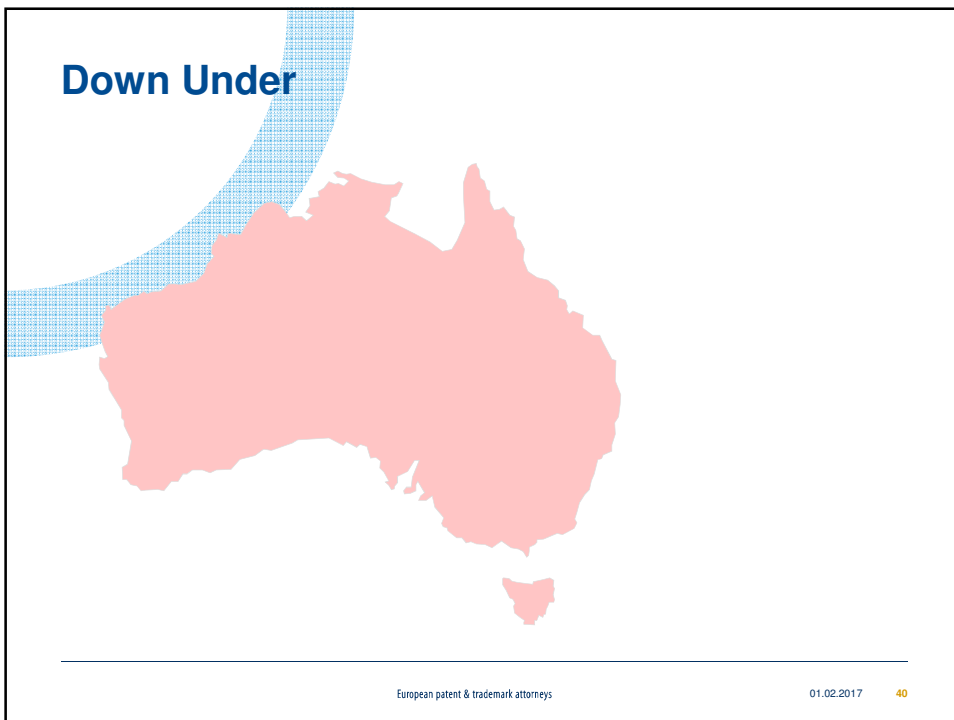
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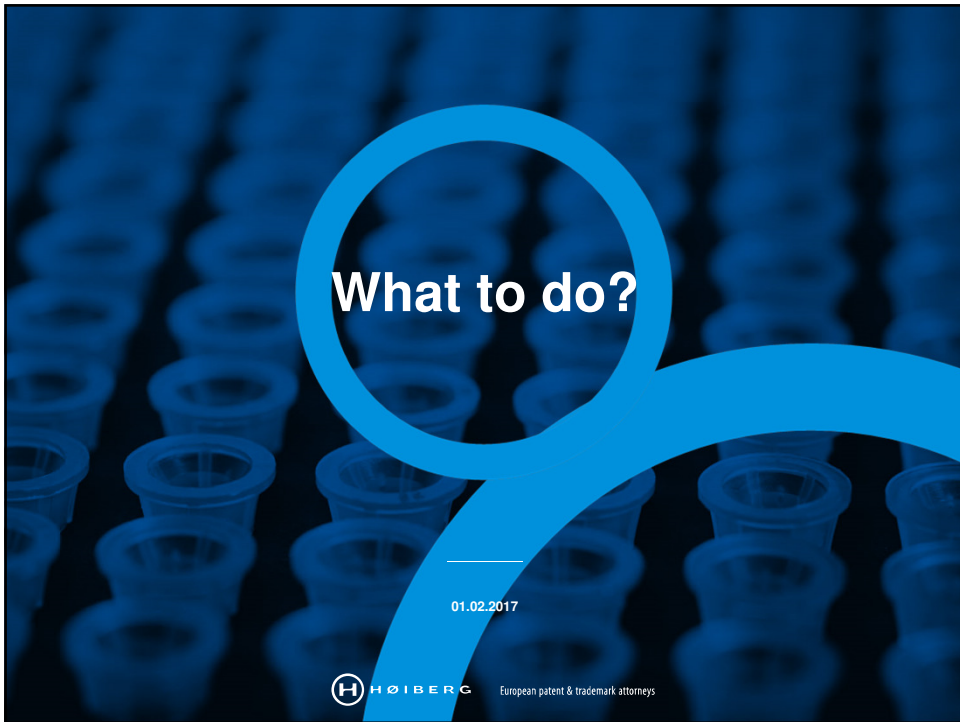
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Diagnostics


 HØIBERG European patent & trademark attorneys 01.02.2017 45

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Measure the marker using MS, HPLC or similar "high tech"

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 HØIBERG European patent & trademark attorneys 01.02.2017 46

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**Thank you
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Exceptions to Patentability

What cannot be done

Jens Viktor Nørgaard
01.02.2017

 HØIBERG European patent & trademark attorneys

Speaker / CV



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 HØIBERG European patent & trademark attorneys 01.02.2017

Agenda

Stem cells
Plant varieties
Products of nature
Laws of nature
Abstract ideas

Why Exceptions



- Ethics, morale
- Non-technical
- Alternative types of protection
- Courts' interpretation of the law
- Public/lobbyist pressure

East meets West

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Common law country

Governed by

- the law
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New plant varieties can be Protected (UPOV; CPVO)

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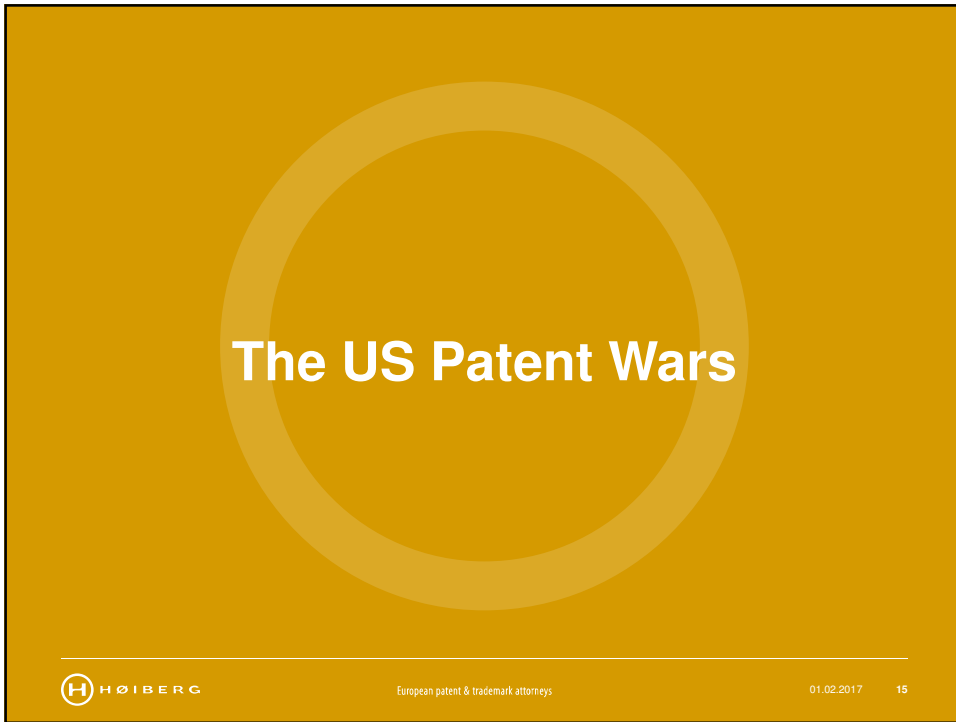
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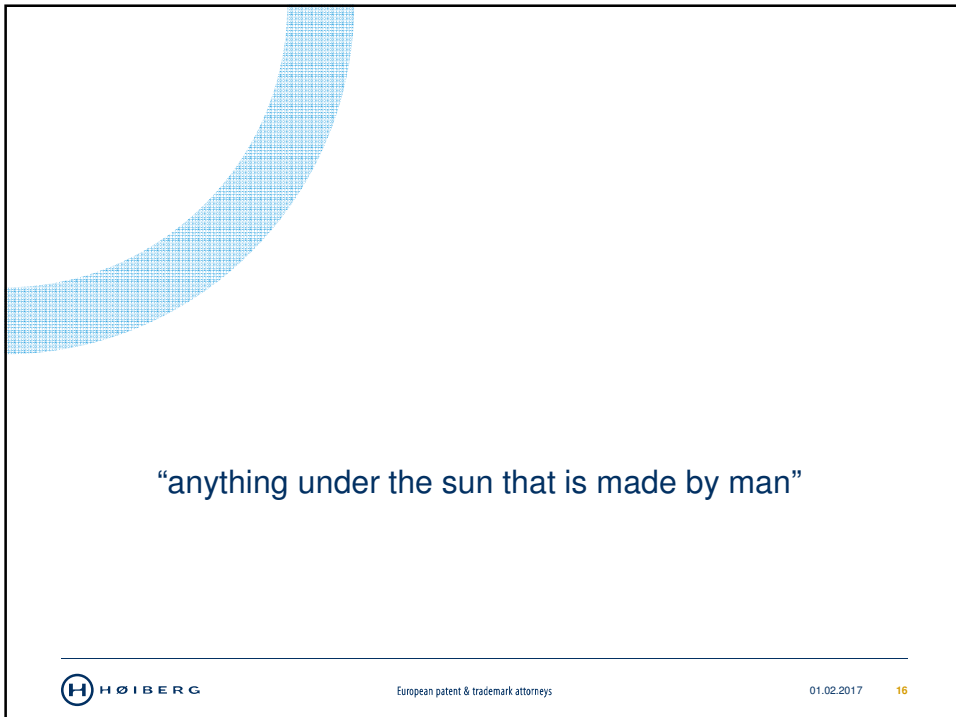
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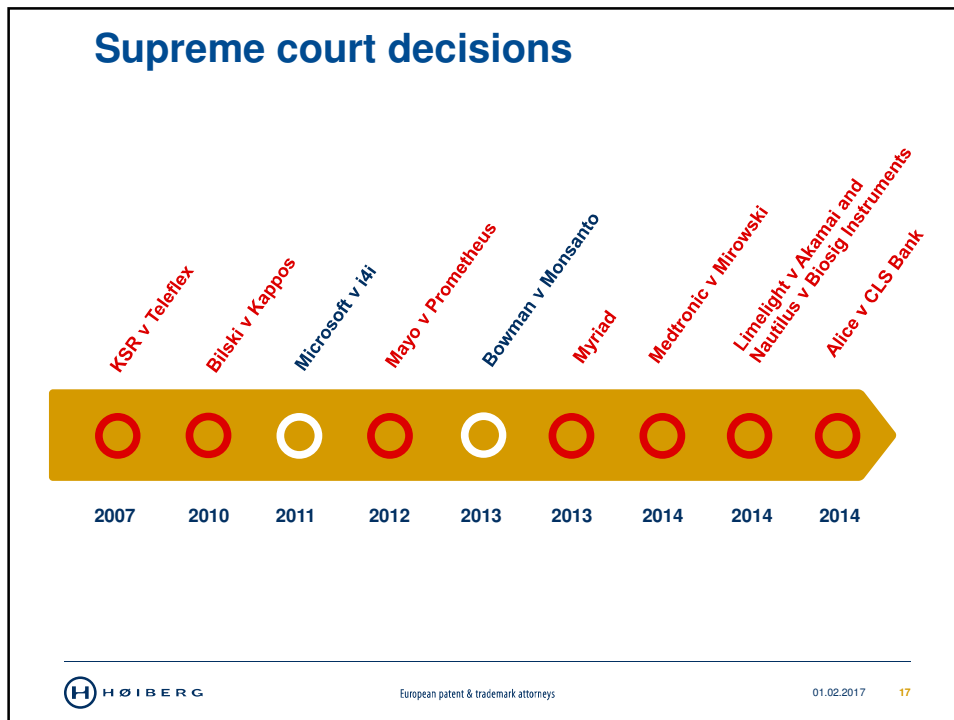
The US Patent Wars

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“anything under the sun that is made by man”

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What does the law say

Patent eligible subject matter (§ 101):
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- The method involved:
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 HØIBERG European patent & trademark attorneys 01.02.2017 21

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- It is important to note what is *not* implicated by this decision.
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Amazonian cherry tree grows wild in Amazonas

It's leaves contain a substance that has anti-cancer effects

Nobody has succeeded in isolating the compound

Amazonic acid background

Applicant has isolated amazonic acid

Has demonstrated effect in treatment of breast and colon cancer

Has created deoxy amazonic acid, with same activity as amazonic.

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- Claim 1: Purified amazonic acid
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1. A composition comprising pomelo juice, and a an effective amount of a preservative.
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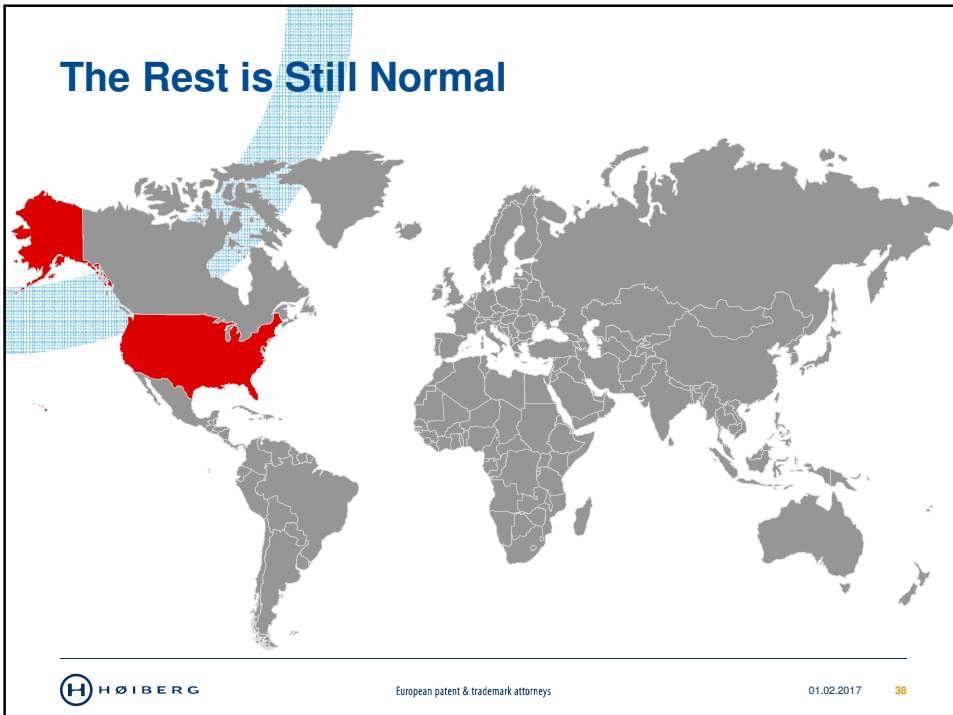
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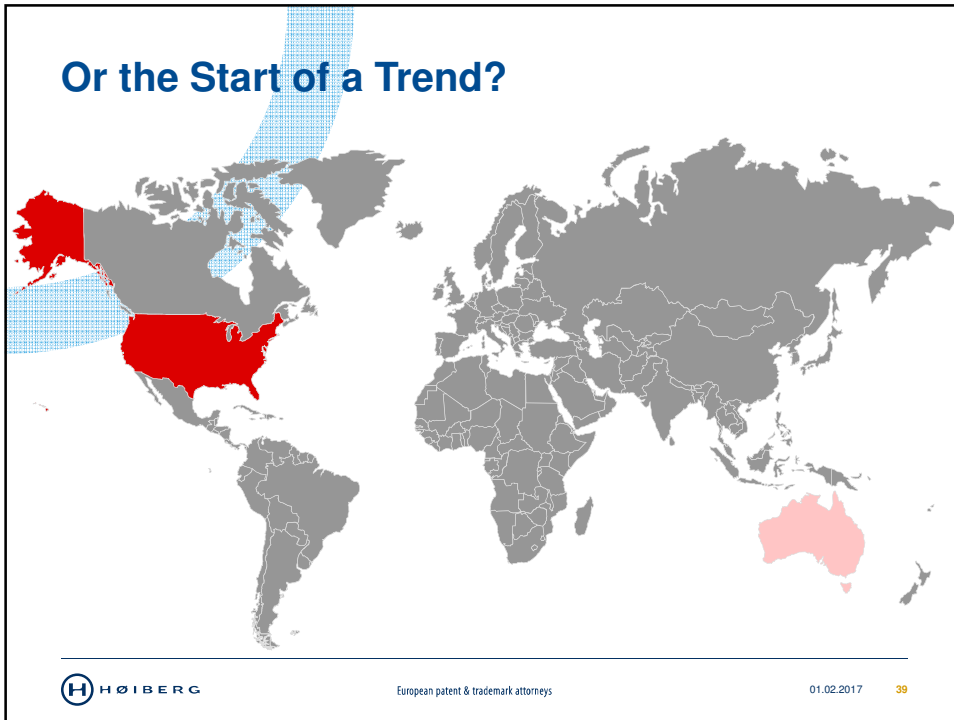
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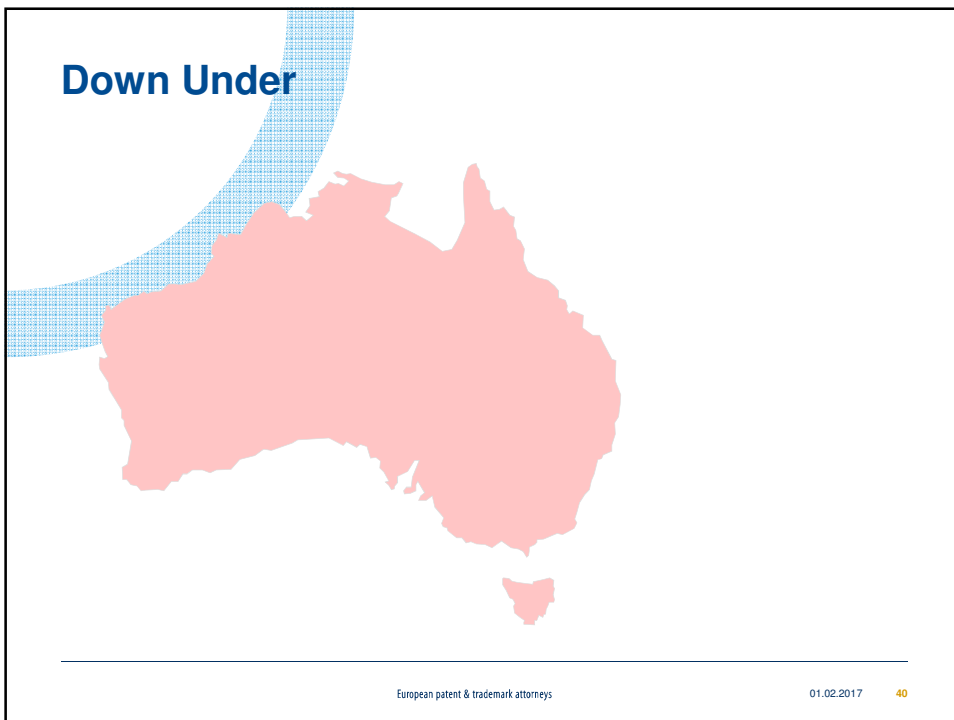
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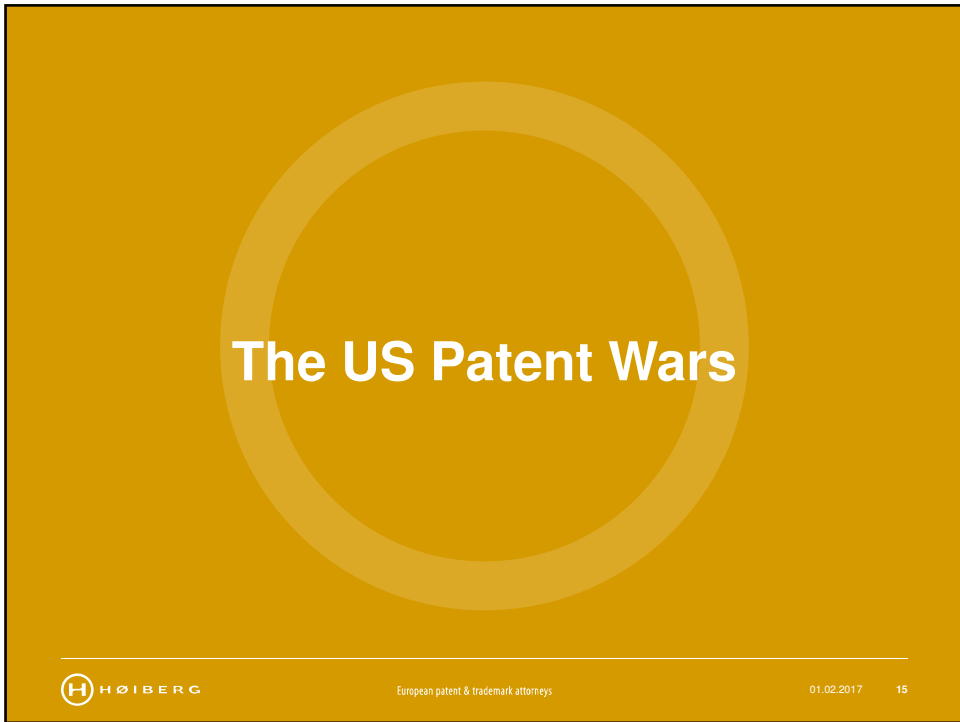
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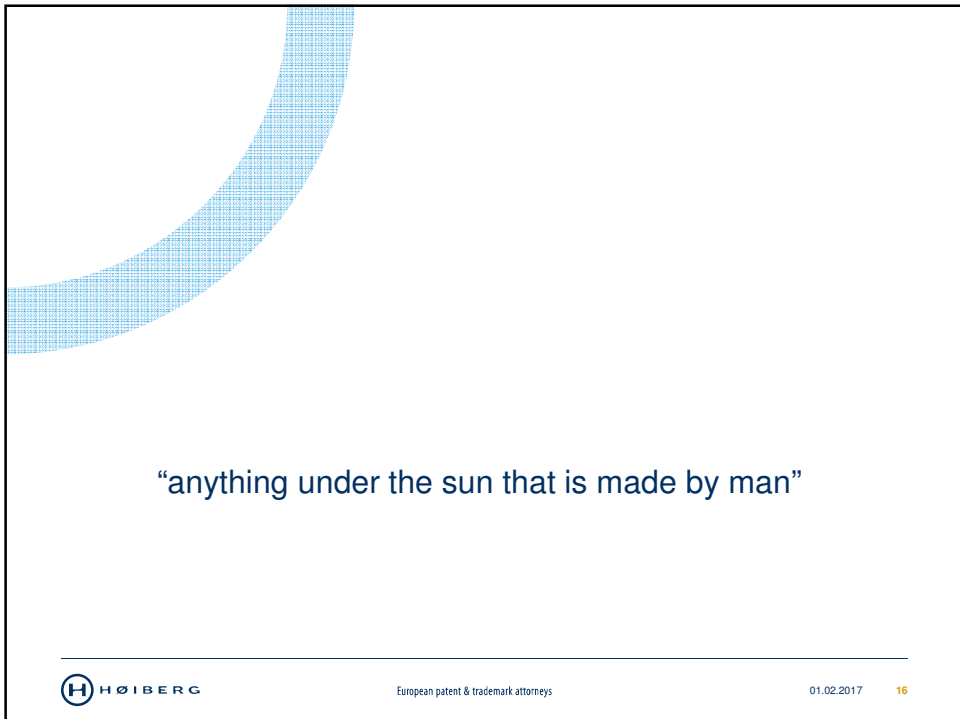
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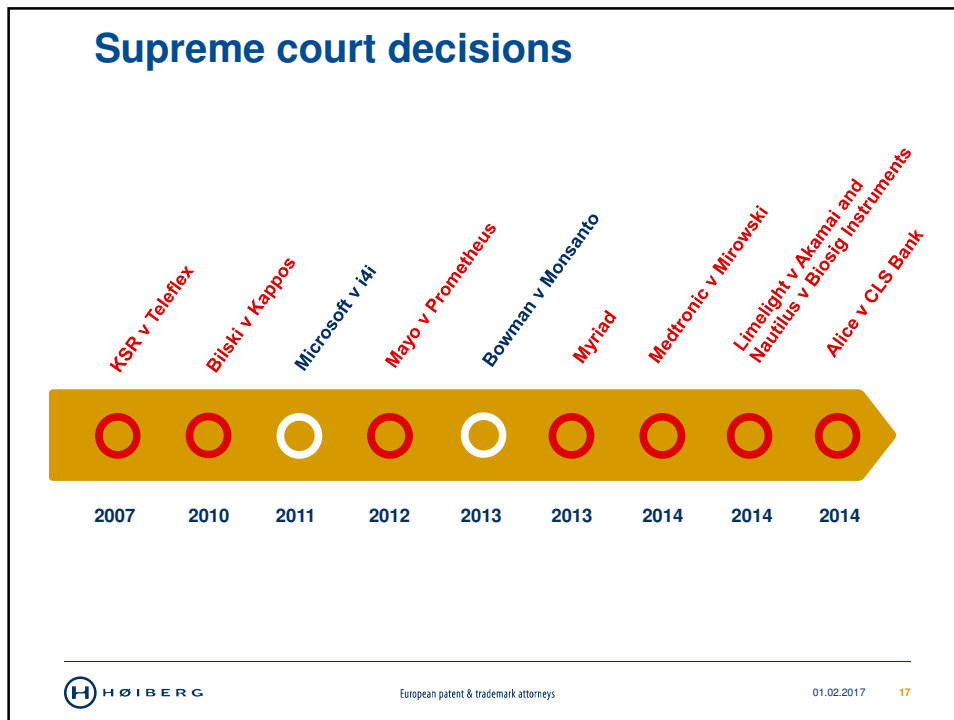
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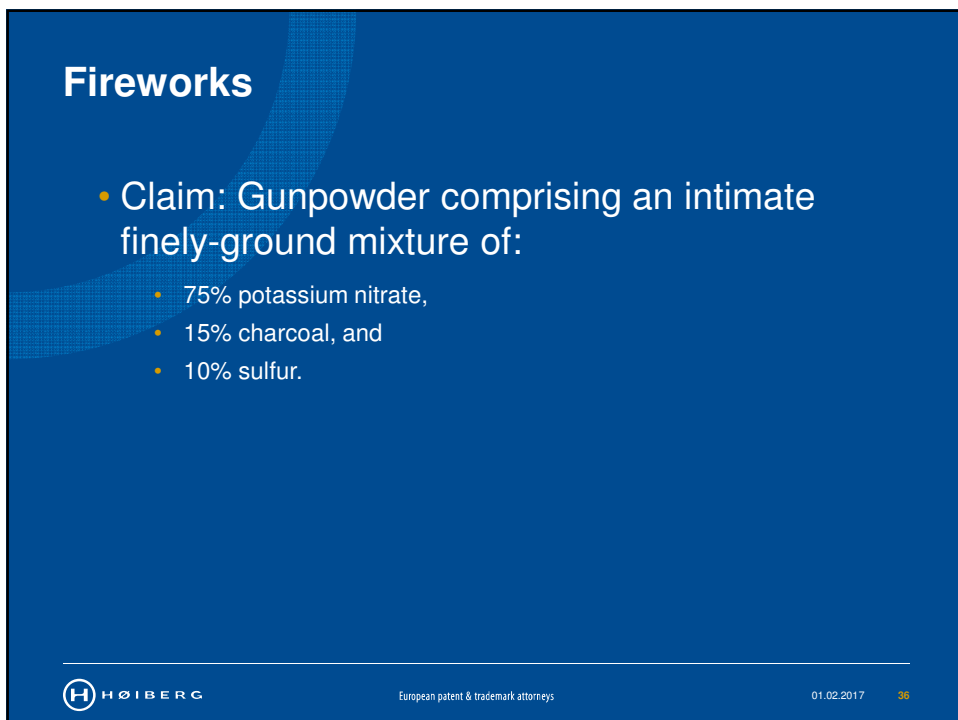
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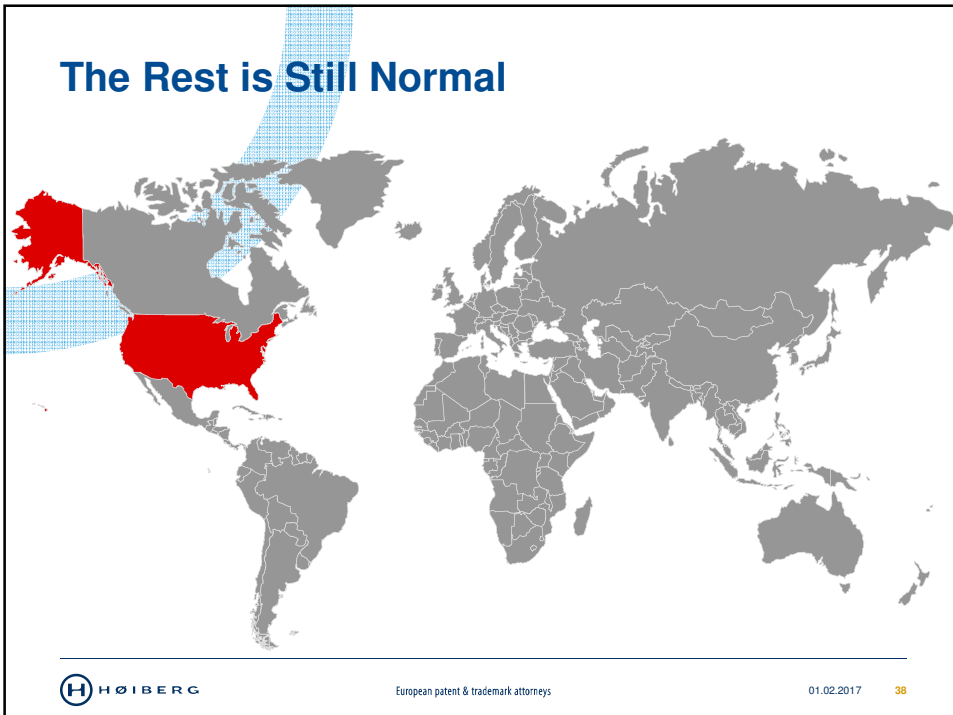
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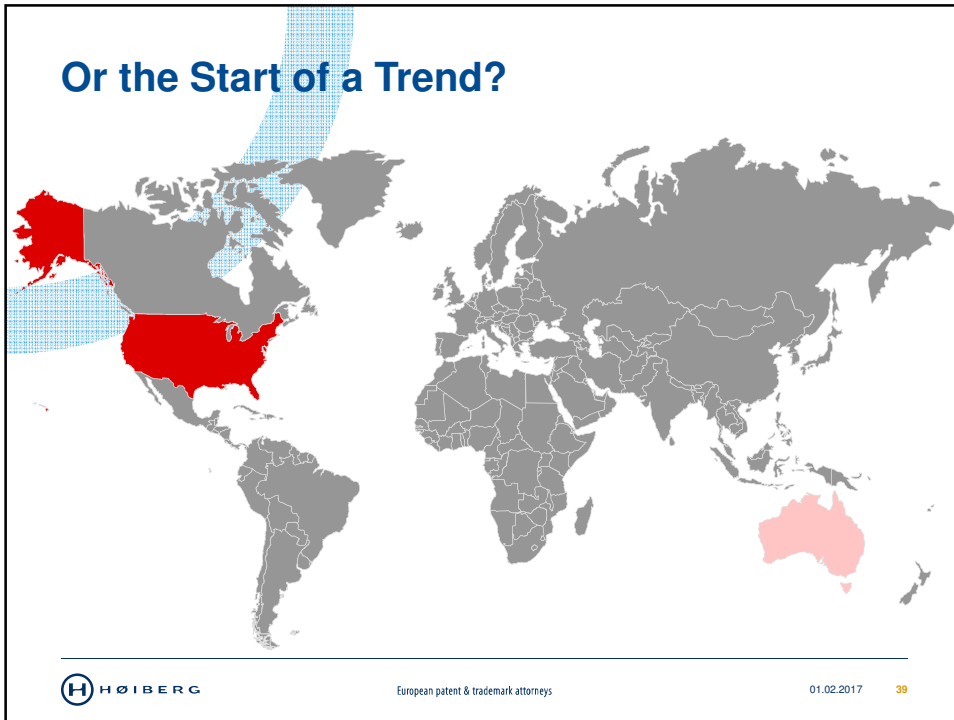
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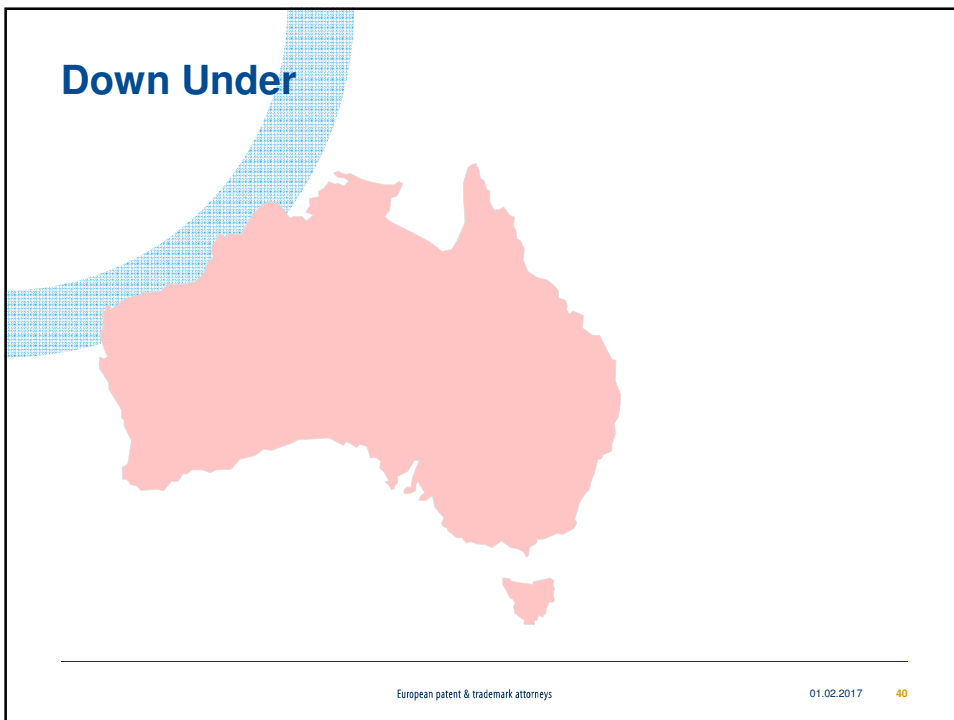
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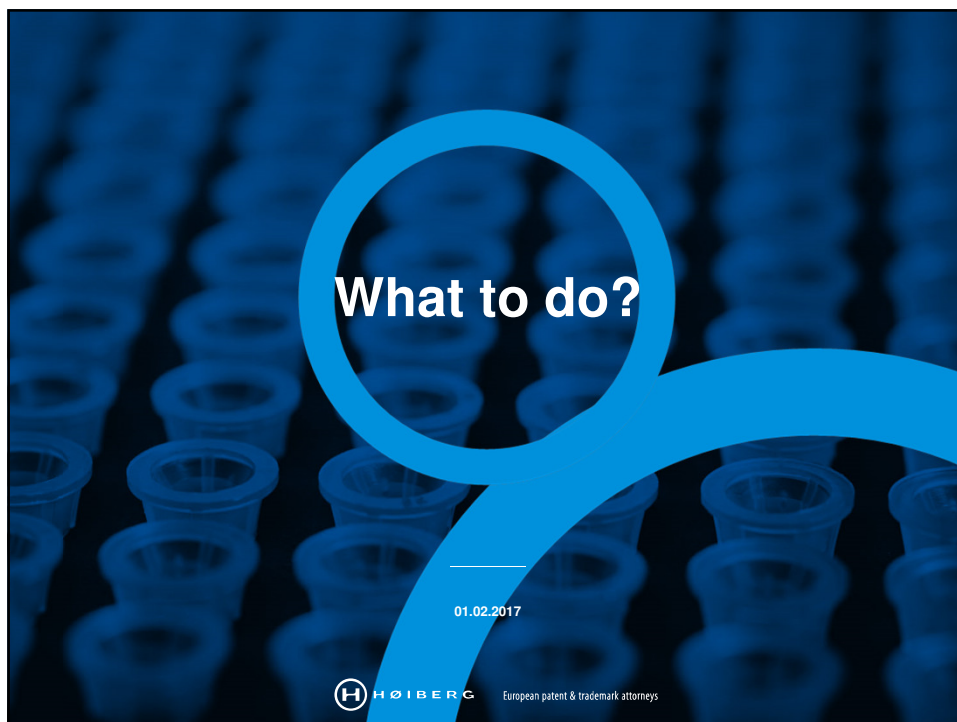
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- Ethics, morale
- Non-technical
- Alternative types of protection
- Courts' interpretation of the law
- Public/lobbyist pressure

East meets West

USA

Common law country

Governed by

- the law
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Europe

Legislator decides

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- Ethics
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Stem cells (European Exemption)

- The law:
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Light at the end of the Tunnel?

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Plant Varieties

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European patent & trademark attorneys
01.02.2017 9

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Plant Varieties - Background

New plant varieties can be Protected (UPOV; CPVO)

European exception

Breeder's & farmer's privilege

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01.02.2017 10

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Plant Varieties – European Status

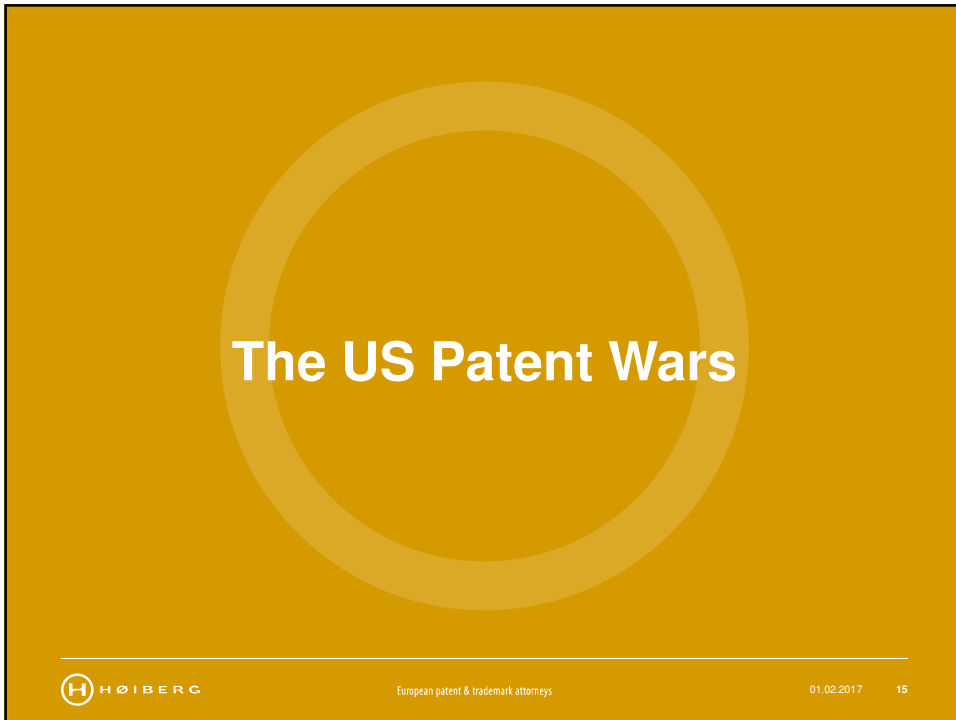
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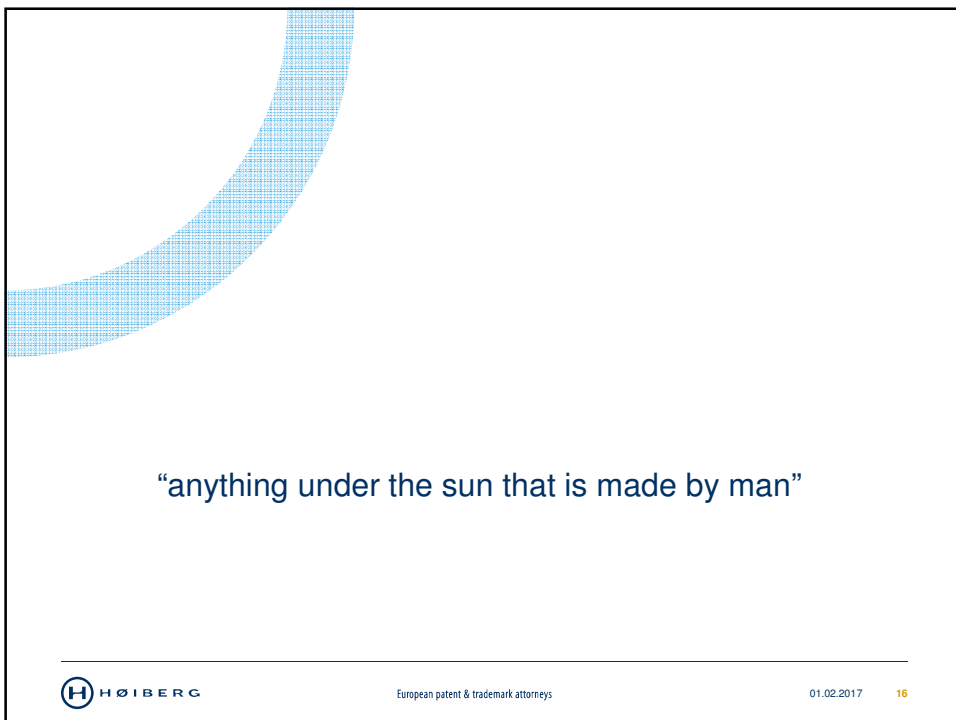
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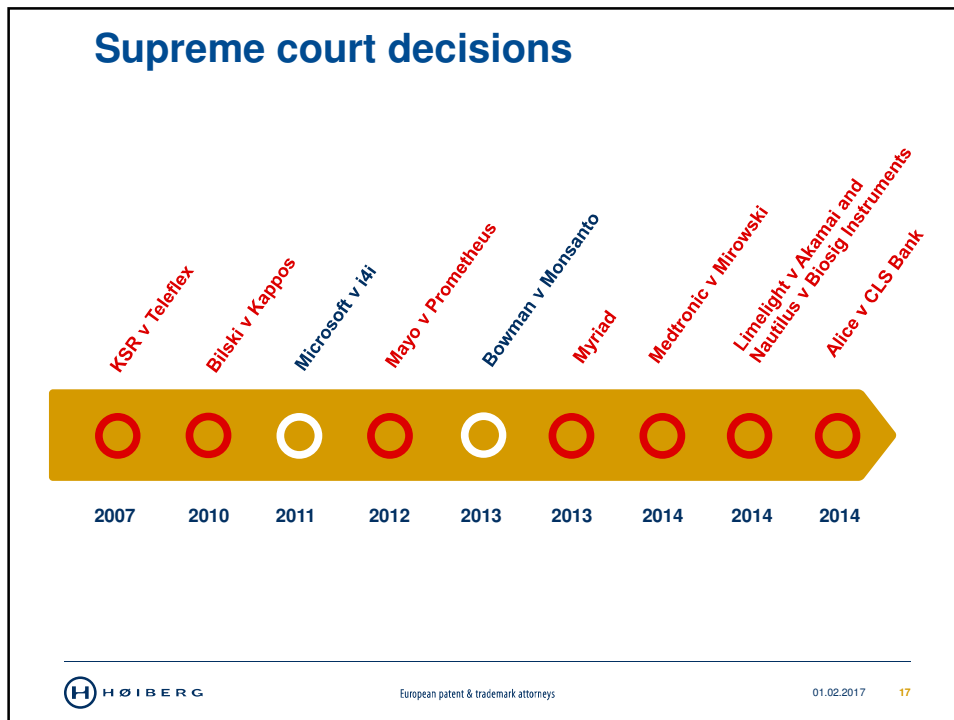
The US Patent Wars

 HØIBERG European patent & trademark attorneys 01.02.2017 15



“anything under the sun that is made by man”

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What does the law say

Patent eligible subject matter (§ 101):
 Whoever invents or discovers any new and useful
process,
machine,
manufacture, or
composition of matter, or
 any new and useful improvement thereof, may obtain a patent
 therefor, subject to the conditions and requirements of this title.

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Mayo vs. Prometheus

- Prometheus Labs had rights to a series of US patents directed to a diagnostic method.
- The method involved:
 - Determining the level of metabolites of thiopurines
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- Prometheus sued Mayo Medical Laboratories for infringement of their US patents

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There is a danger that granting patents that tie up use of laws of nature will inhibit future innovation

Provides incentives that lead to creation, invention and discovery

Patent protection is a two-edged sword


Consequences

- No diagnostic patents are granted
- Diagnostic correlation = "law of nature"
- The detection method must be patentable in itself

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Myriad

- Myriad Genetics proprietor to a number of US patents
- Patent claims:
 - "isolated" human deoxyribonucleic acid (DNA) sequences "BRCA1" and "BRCA2"; and
 - mutations associated with predisposition to breast and ovarian cancers

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- It is important to note what is *not* implicated by this decision.
- This case does not involve patents on new *applications* of knowledge about the BRCA1 and BRCA2 genes.
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- No patents on naturally occurring products
- Recombinant proteins
- Small molecules
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Claim 18. A method to enable the formulation of customized multi-party risk management contracts having a future time of maturity, the method comprising the steps of:

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Examples from Guidelines and Training materials

- Amazonic acid (anticancer drug from plant)
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- Gunpowder

Amazonic acid background

Amazonian cherry tree grows wild in Amazonas

It's leaves contain a substance that has anti-cancer effects

Nobody has succeeded in isolating the compound

Amazonic acid background

Applicant has isolated amazonic acid

Has demonstrated effect in treatment of breast and colon cancer

Has created deoxy amazonic acid, with same activity as amazonic.

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- Claim 1: Purified amazonic acid
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Claim 1 is not patentable. Separating the acid from its surrounding material in the leaf has resulted in the purified amazonic acid having not markedly different characteristics from its naturally occurring counterpart.

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Pomelo Juice

1. A composition comprising pomelo juice, and a an effective amount of a preservative.
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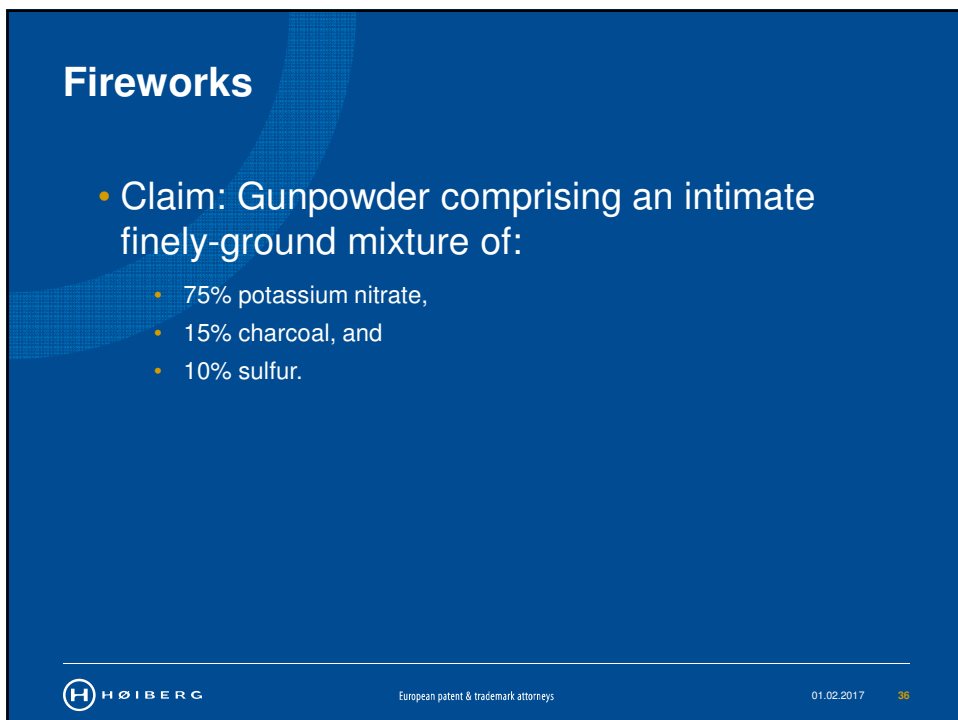


Gunpowder

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Fireworks

- Claim: Gunpowder comprising an intimate finely-ground mixture of:
 - 75% potassium nitrate,
 - 15% charcoal, and
 - 10% sulfur.

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We have an Invention!

This claim is patentable.

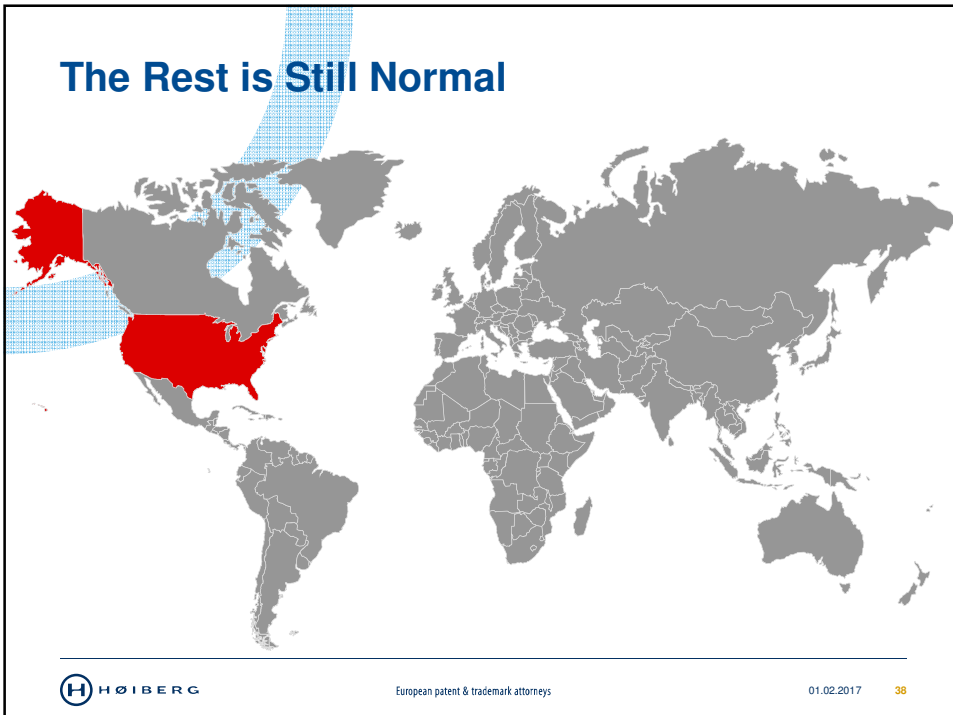
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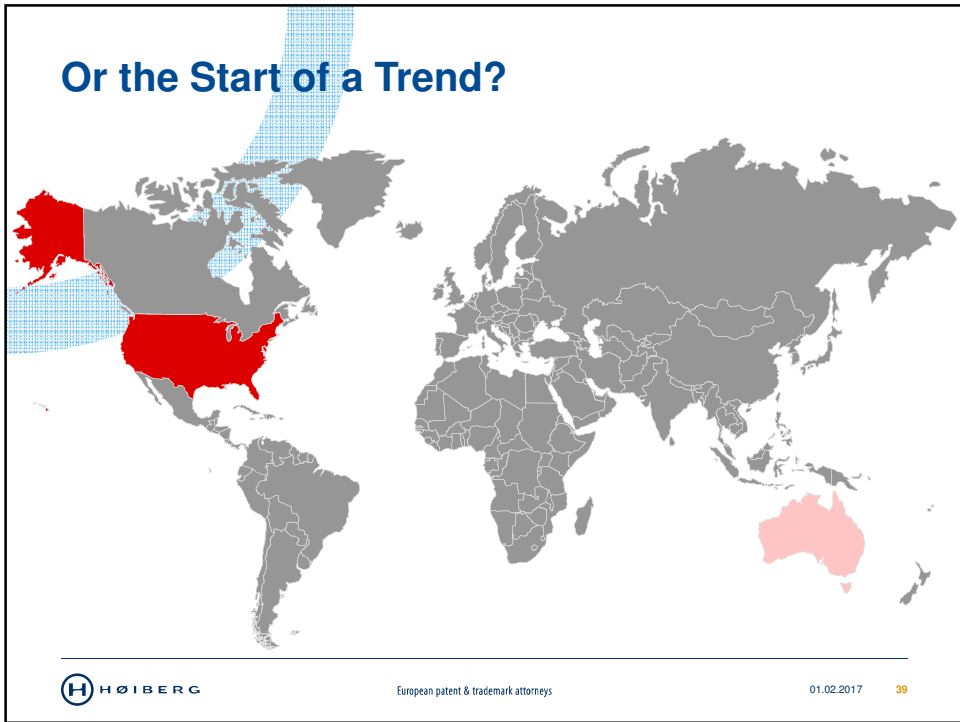
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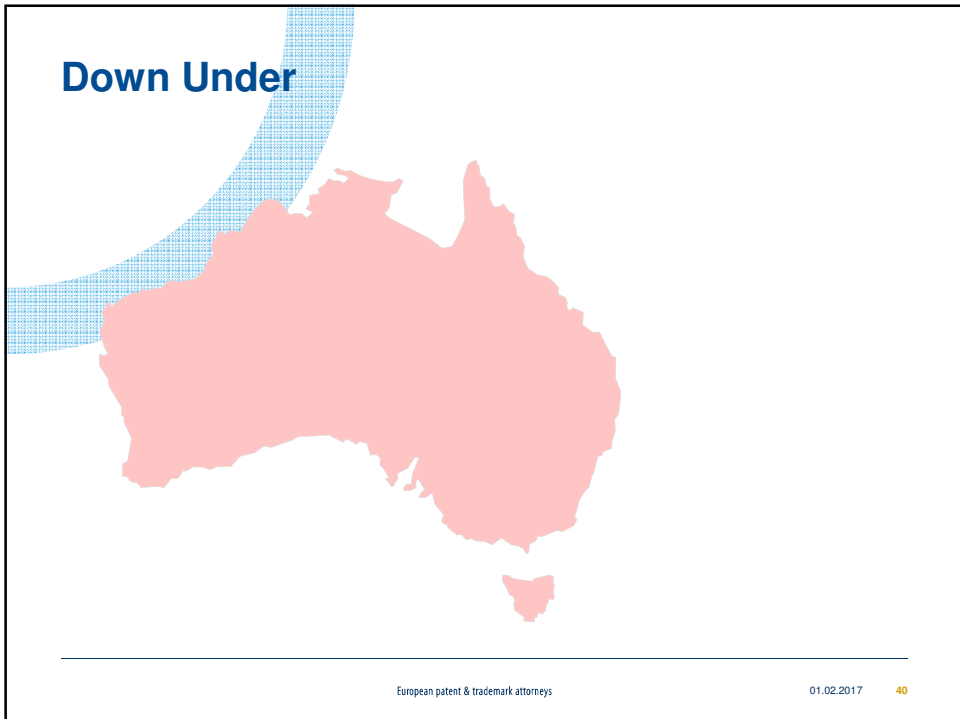
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European patent & trademark attorneys
01.02.2017 39

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European patent & trademark attorneys
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Recent Decision from AU High Court


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- Proteins and peptides are patentable
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- Diagnostic methods are patentable
- Methods of treatment are patentable



Diagnostics


 HØIBERG European patent & trademark attorneys 01.02.2017 45

Diagnostics

Focus on new and patentable analytical methods

Measure the marker using MS, HPLC or similar "high tech"

Recite all steps of analytical method (e.g. PCR, Elisa)

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e.g. add a method of treatment step at the end (if tested positive for condition X, treat with drug Y)

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- No patents on plants, seeds, or animals
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Exceptions to Patentability

What cannot be done

Jens Viktor Nørgaard
01.02.2017

 HØIBERG European patent & trademark attorneys

Speaker / CV



Jens Viktor Nørgaard

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Plant varieties
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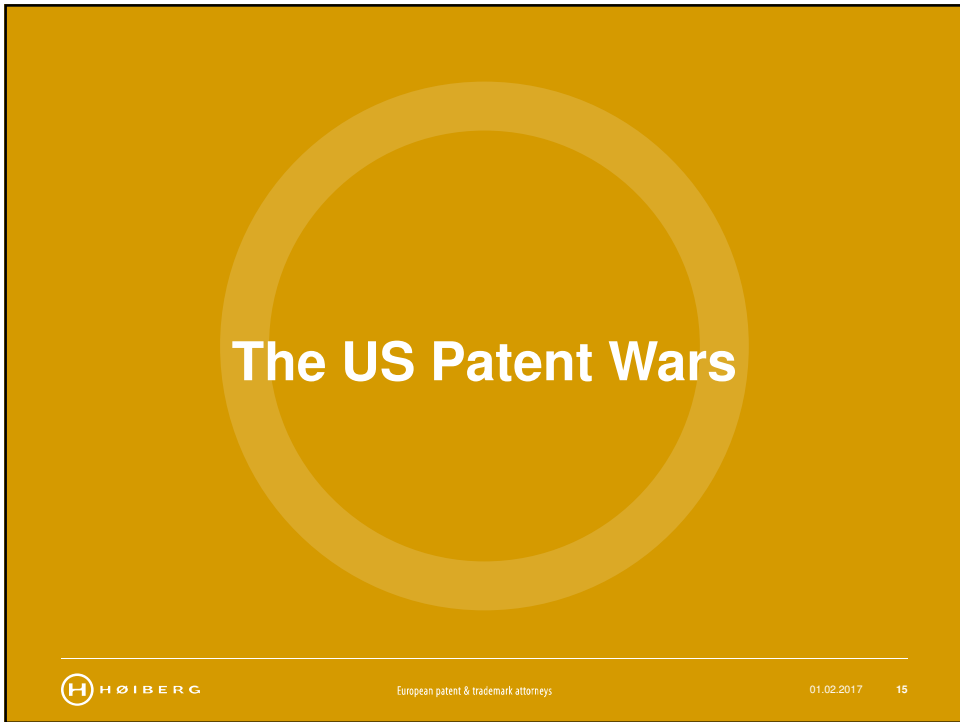
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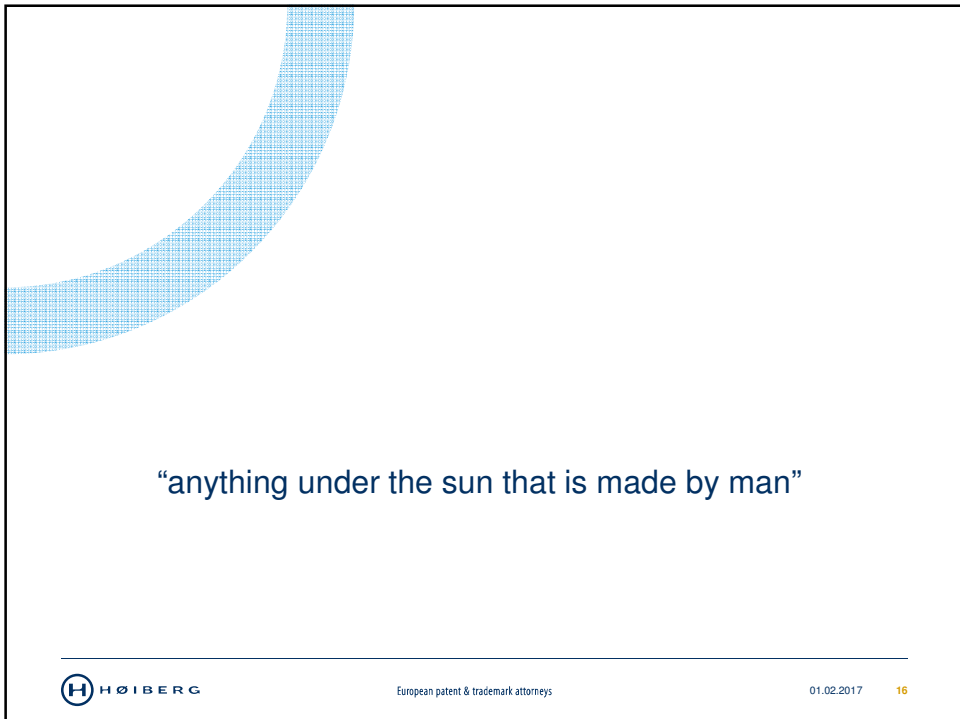
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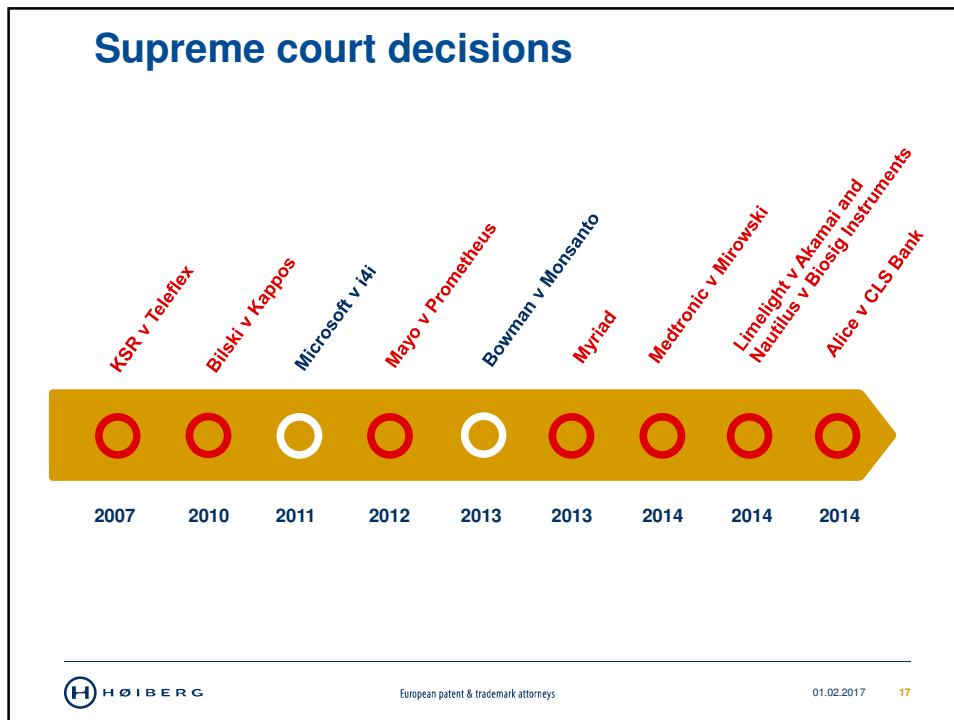
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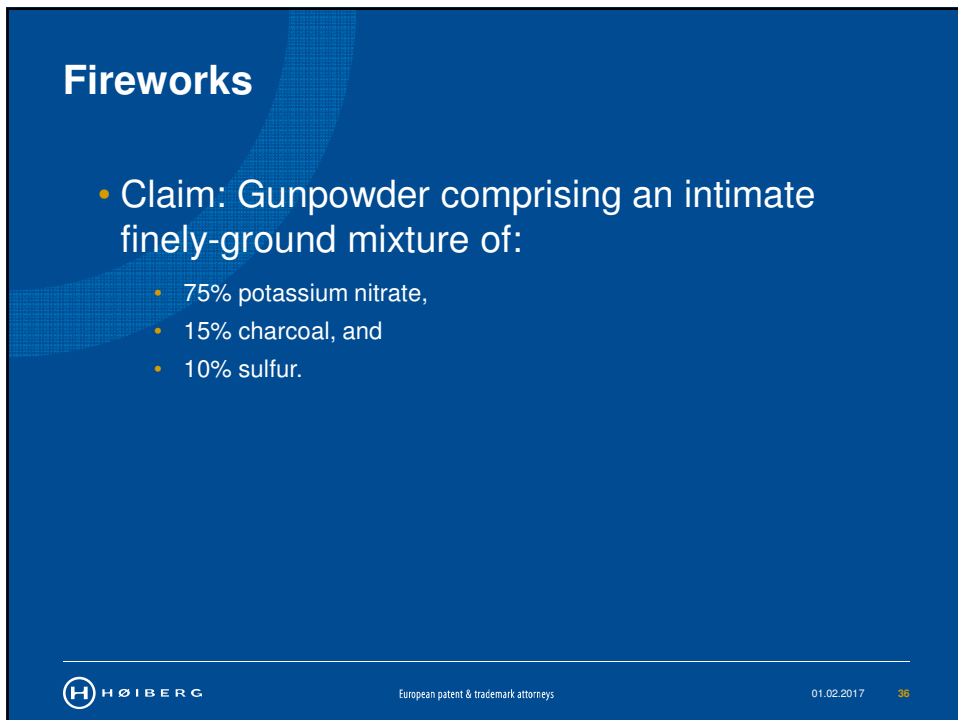
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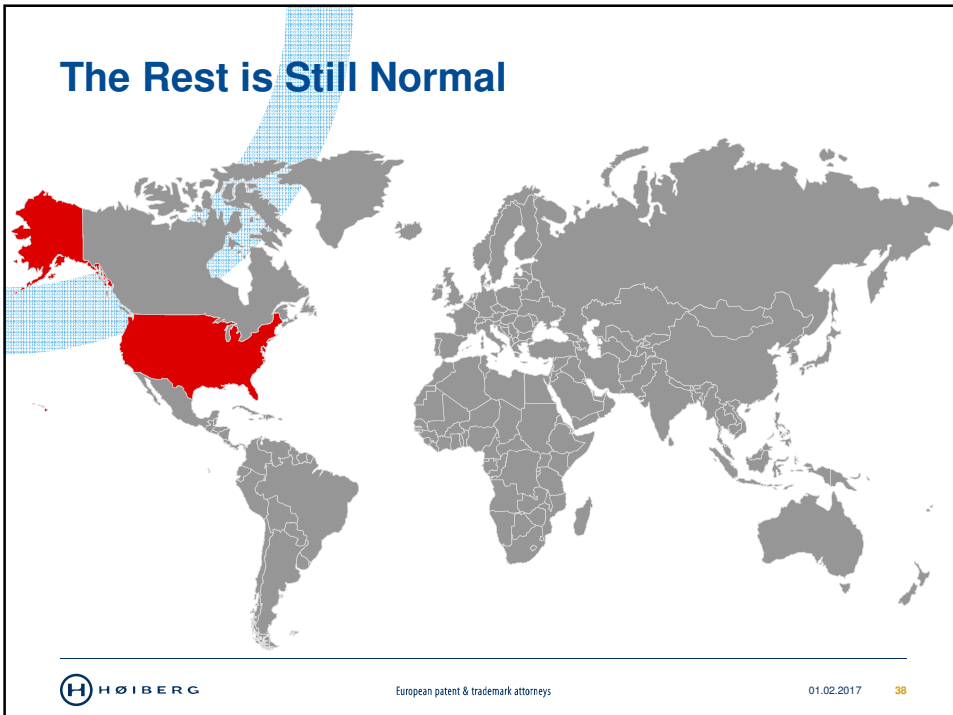
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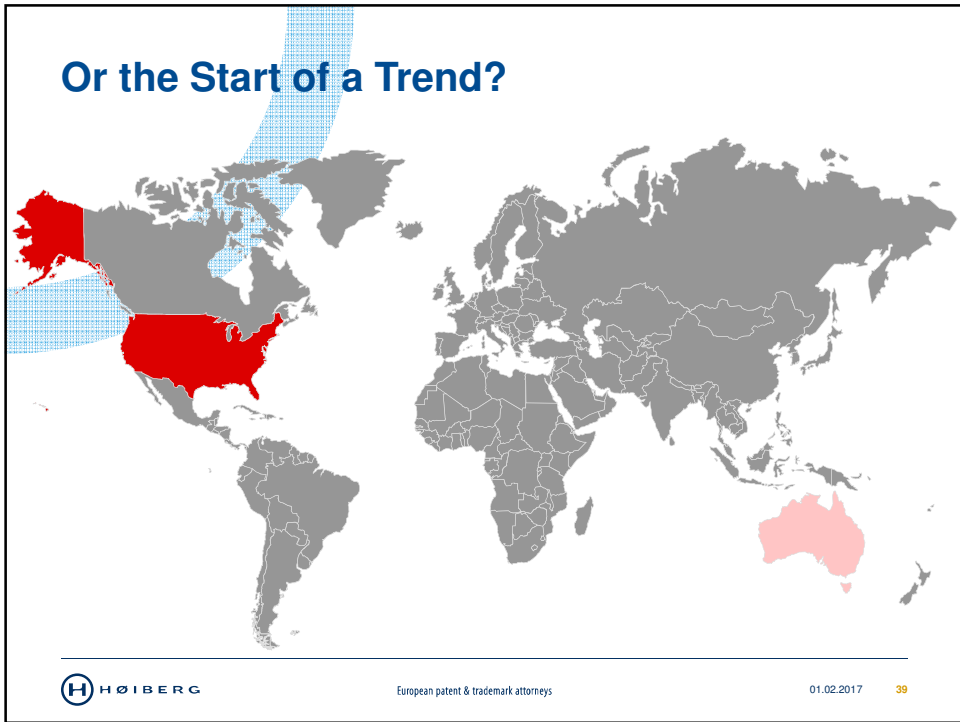
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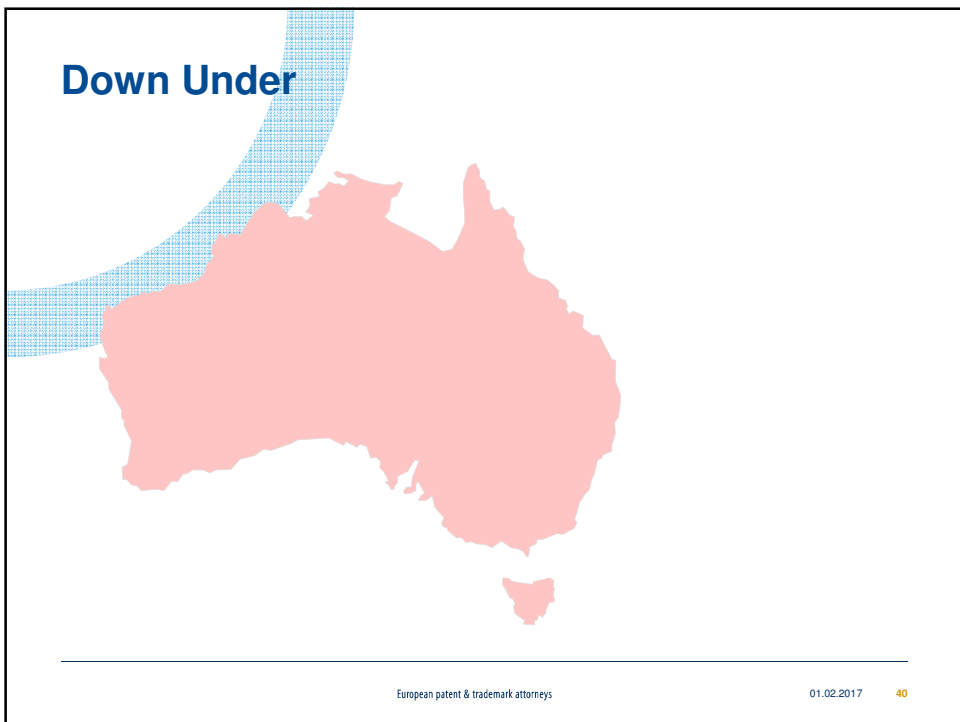
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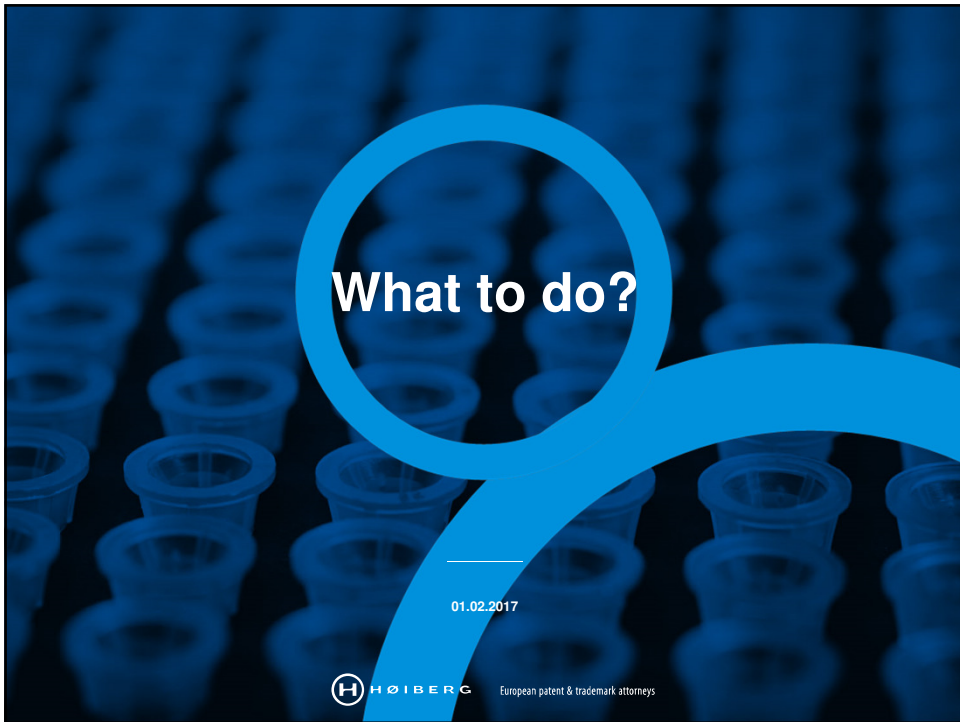
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Speaker / CV



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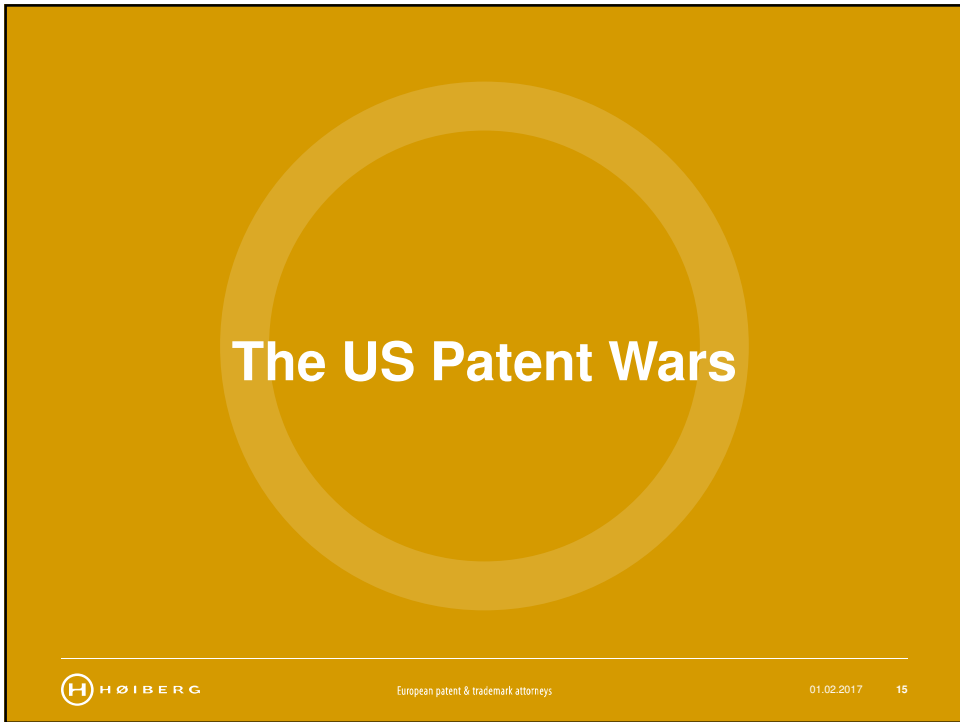
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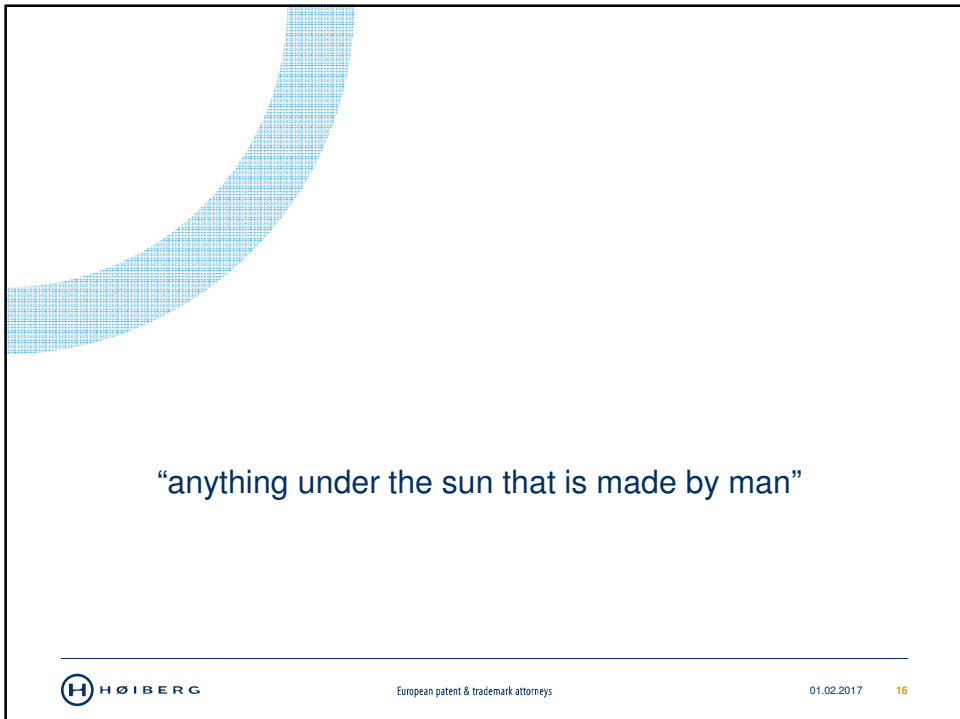
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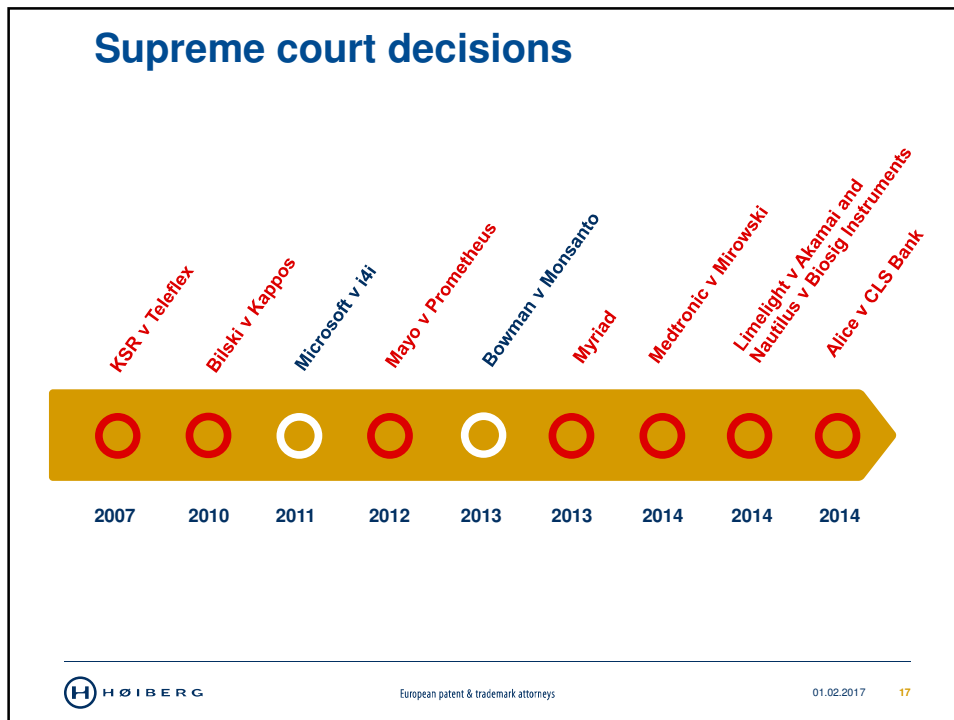
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- No diagnostic patents are granted
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 HØIBERG European patent & trademark attorneys 01.02.2017 21

Myriad

- Myriad Genetics proprietor to a number of US patents
- Patent claims:
 - "isolated" human deoxyribonucleic acid (DNA) sequences "BRCA1" and "BRCA2"; and
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- Small molecules
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- Stem cells
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- Amazonic acid (anticancer drug from plant)
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Amazonic acid background

Amazonian cherry tree grows wild in Amazonas

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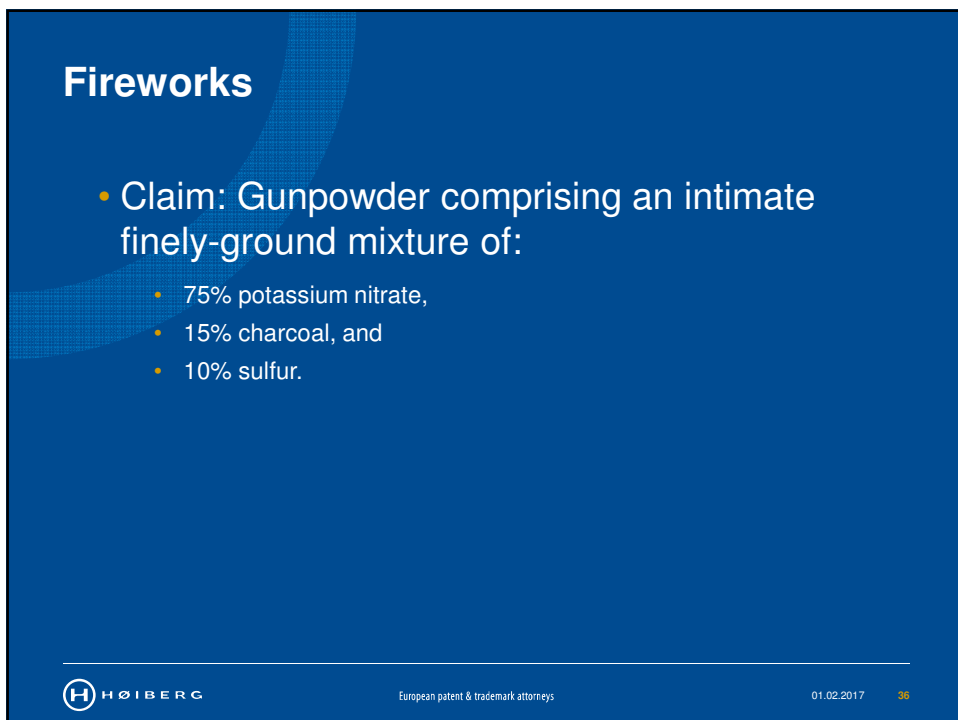


Gunpowder

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Fireworks

- Claim: Gunpowder comprising an intimate finely-ground mixture of:
 - 75% potassium nitrate,
 - 15% charcoal, and
 - 10% sulfur.

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We have an Invention!

This claim is patentable.

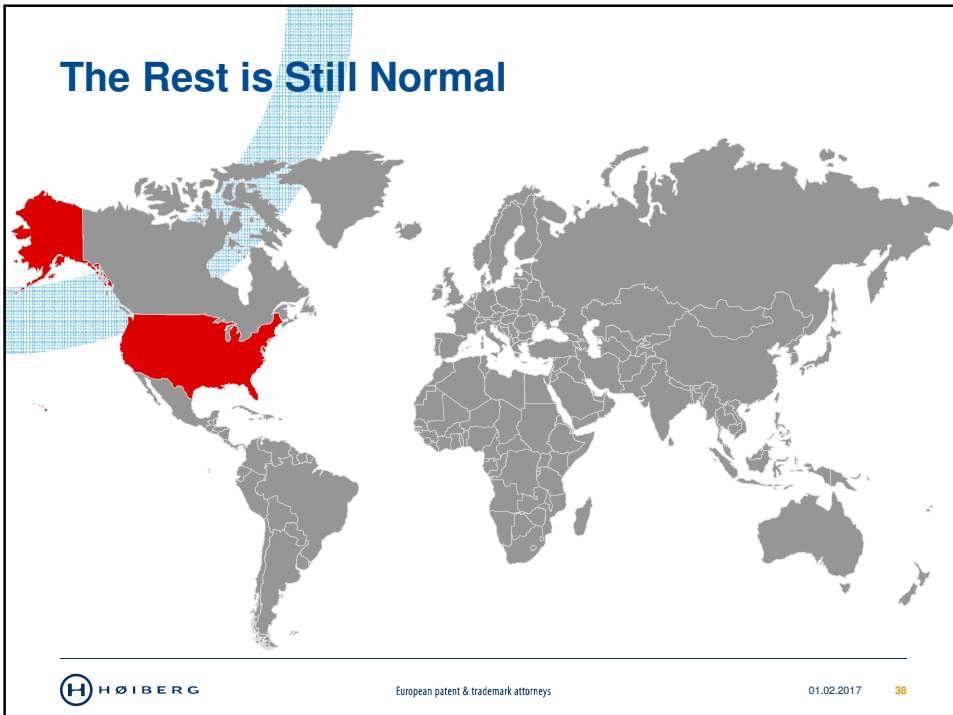
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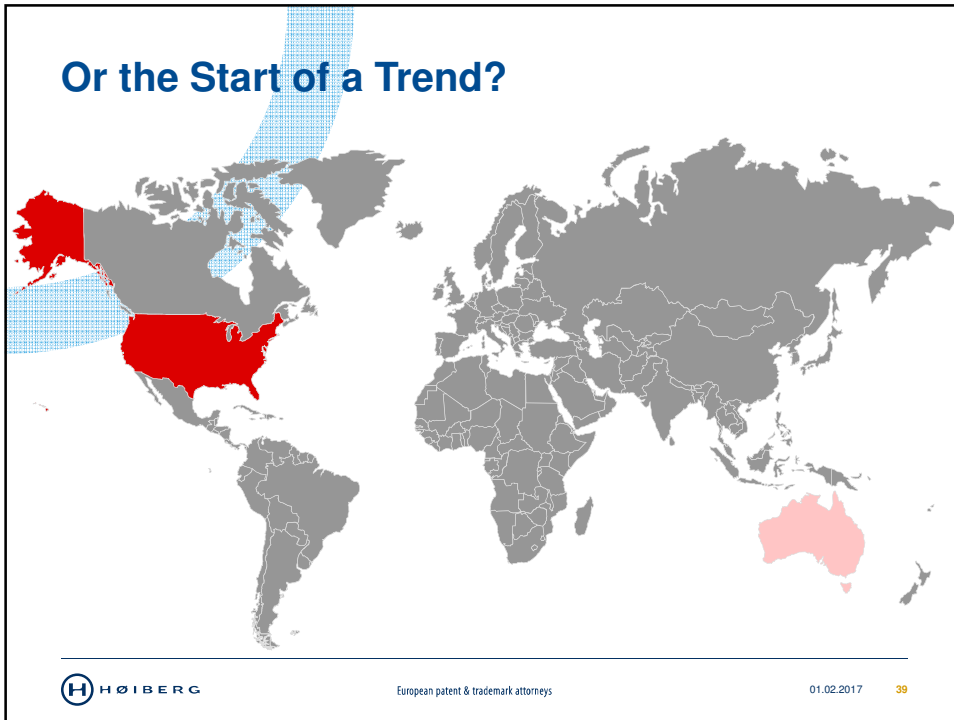
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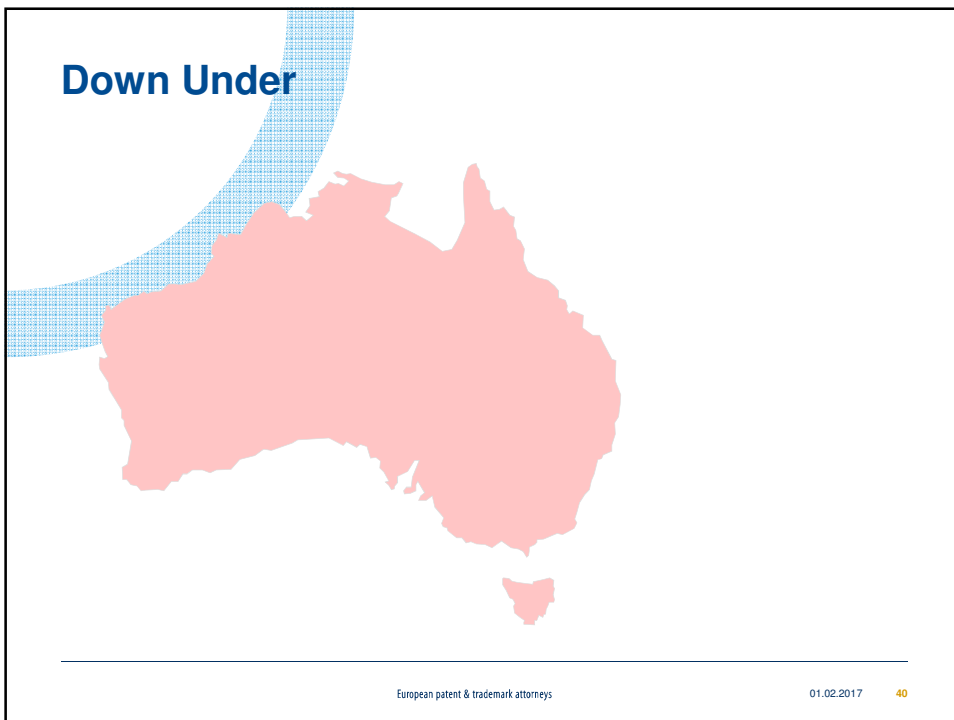
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- Proteins and peptides are patentable
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- Diagnostic methods are patentable
- Methods of treatment are patentable



Diagnostics


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Diagnostics

Focus on new and patentable analytical methods

Measure the marker using MS, HPLC or similar "high tech"

Recite all steps of analytical method (e.g. PCR, Elisa)

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Diagnosis

Tie the diagnostic method to treatment, follow-on diagnostics

e.g. add a method of treatment step at the end (if tested positive for condition X, treat with drug Y)

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- No patents on plants, seeds, or animals
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Exceptions to Patentability

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Jens Viktor Nørgaard
01.02.2017

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Speaker / CV



Jens Viktor Nørgaard

Head of Biotechnology & Plant sciences
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jvn@hoiberg.com

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Agenda

Stem cells
Plant varieties
Products of nature
Laws of nature
Abstract ideas

Why Exceptions



- Ethics, morale
- Non-technical
- Alternative types of protection
- Courts' interpretation of the law
- Public/lobbyist pressure

East meets West

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Common law country

Governed by

- the law
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New plant varieties can be Protected (UPOV; CPVO)

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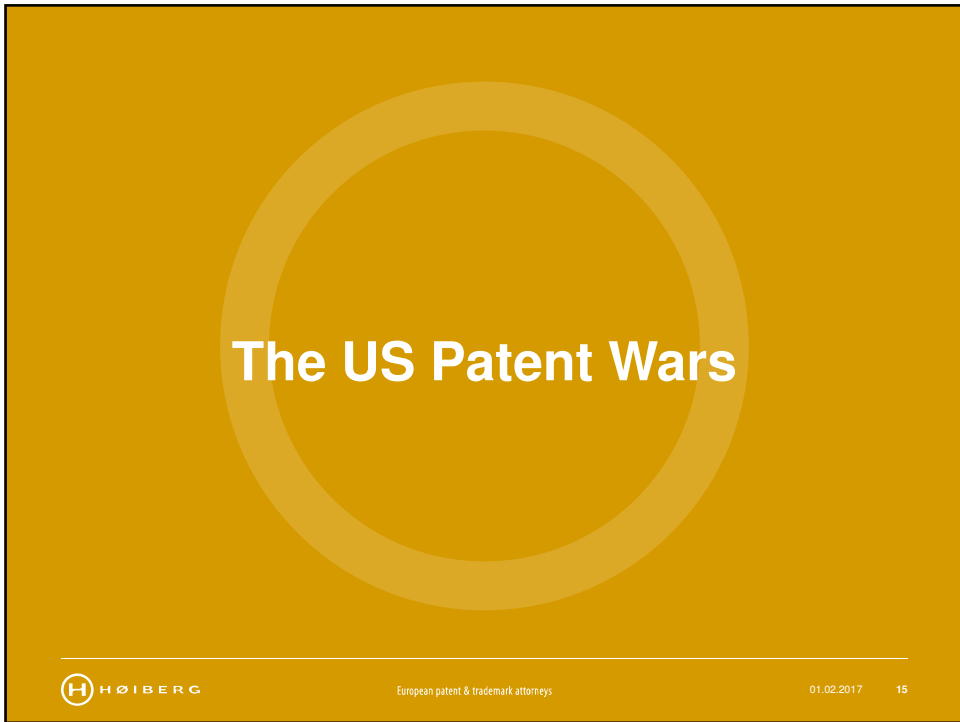
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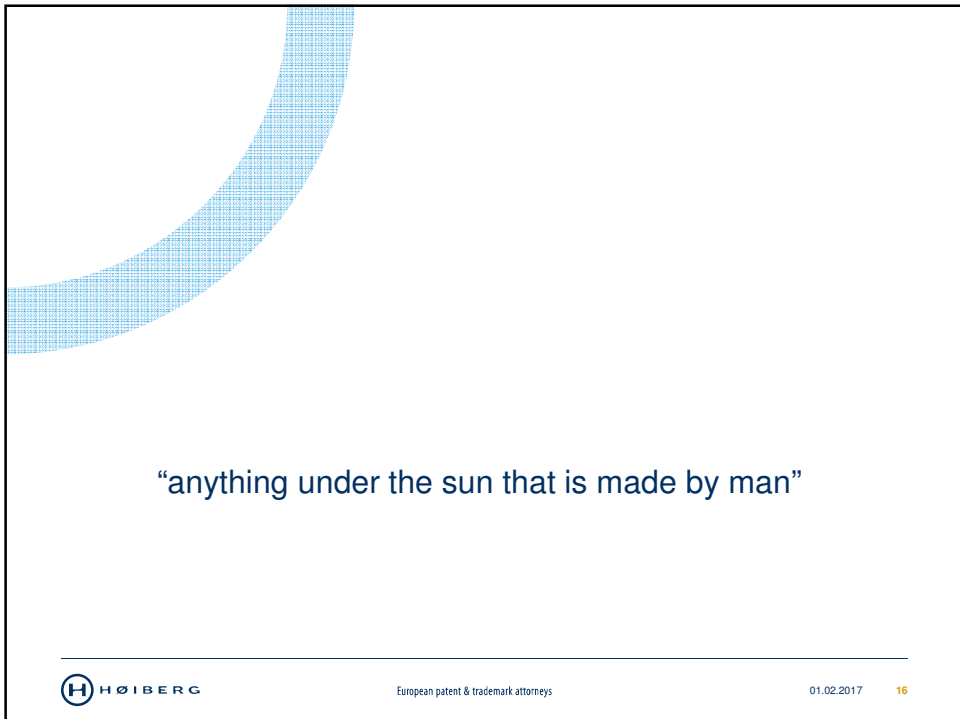
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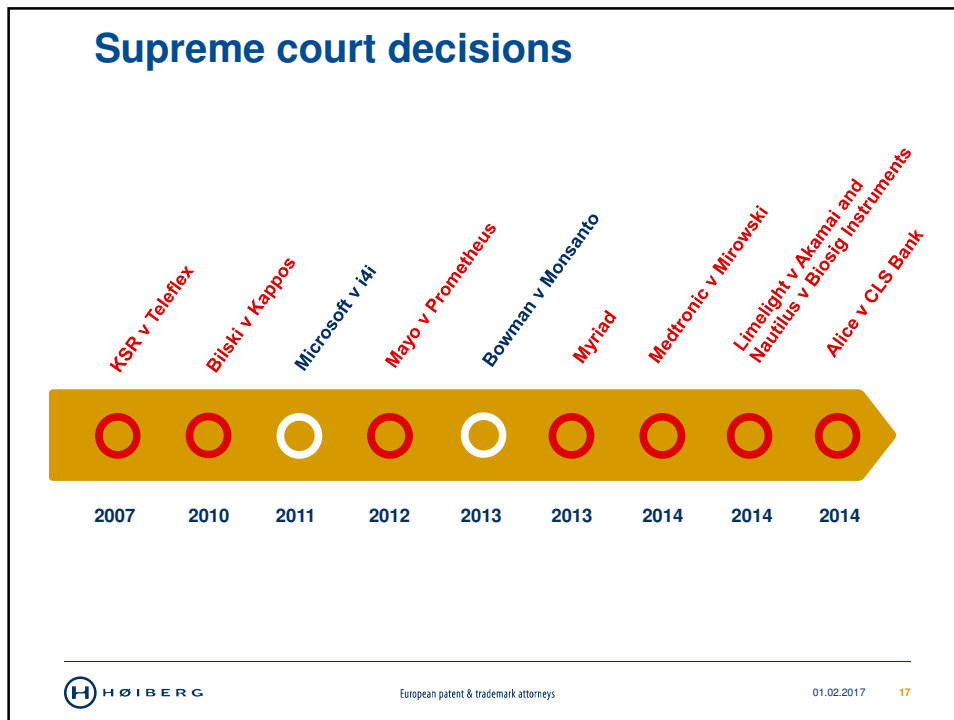
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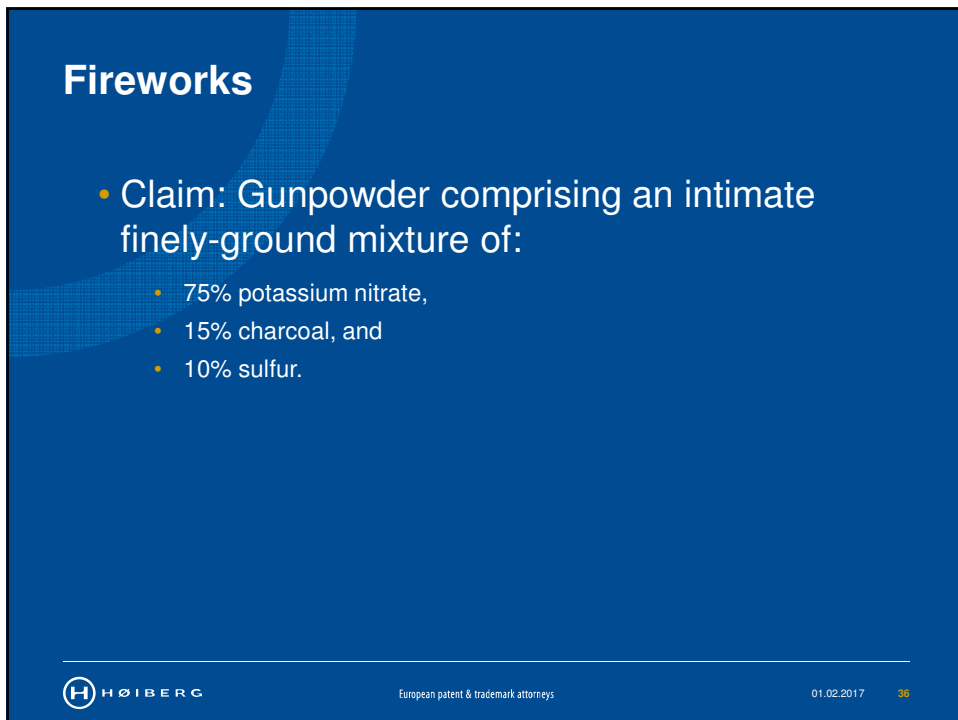
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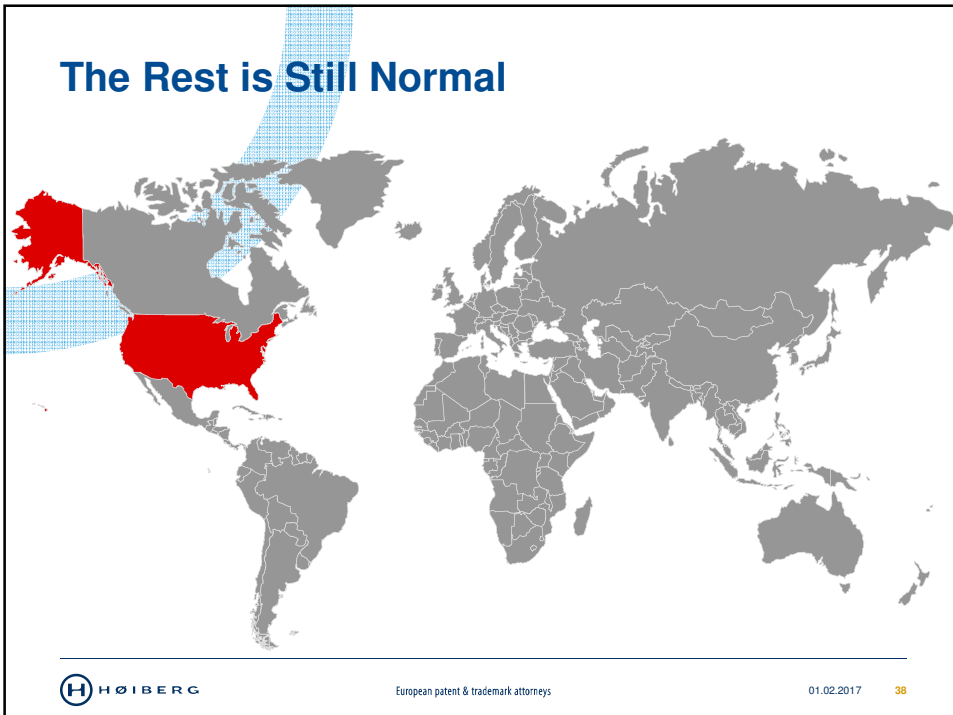
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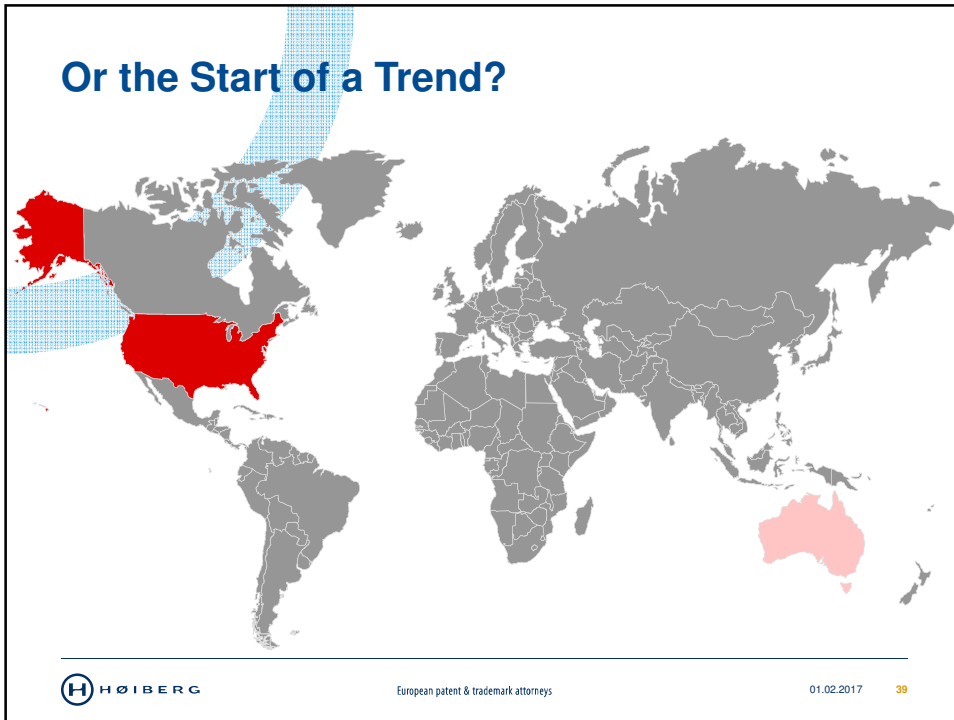
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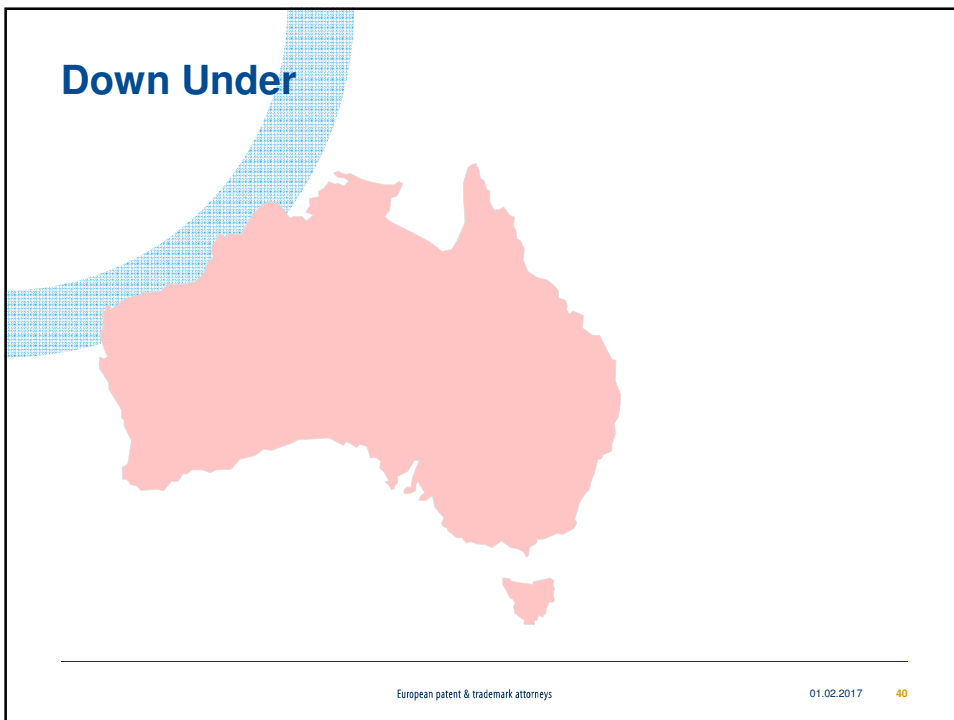
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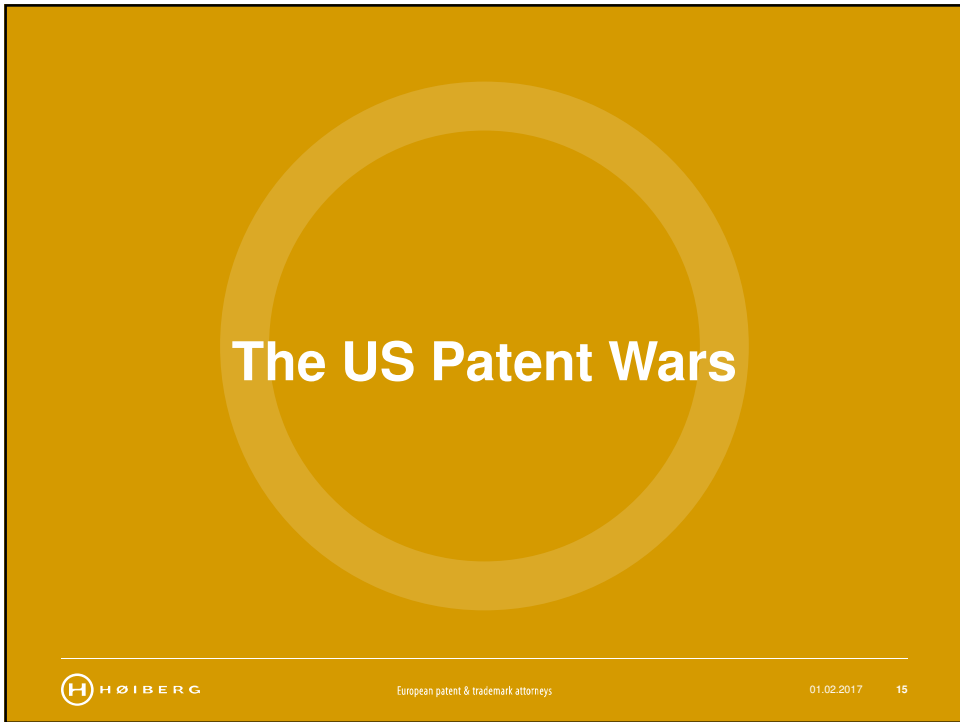
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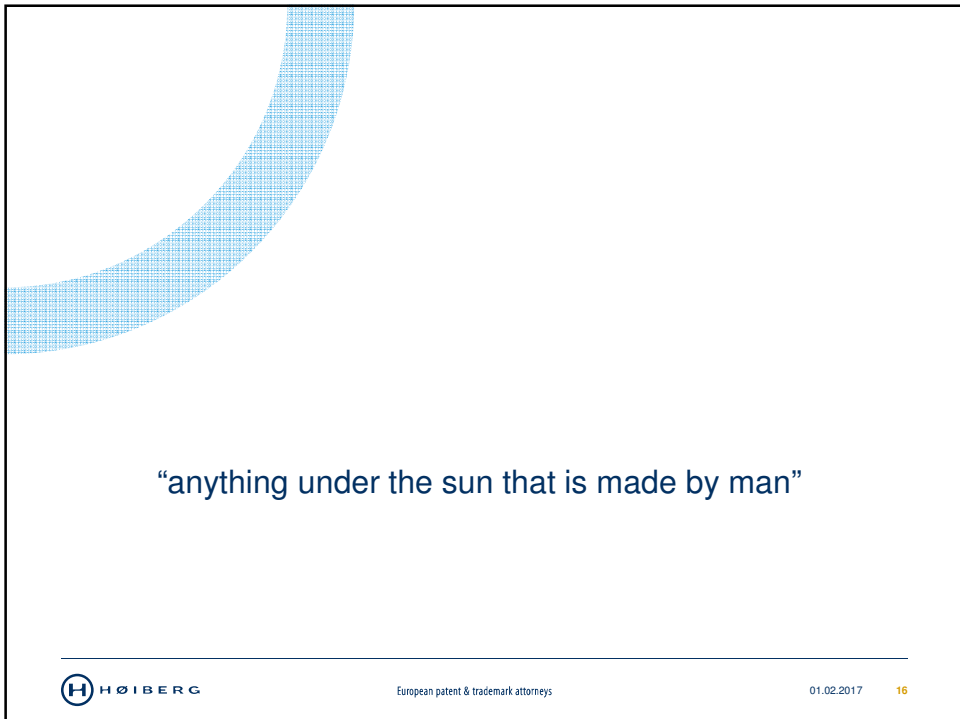


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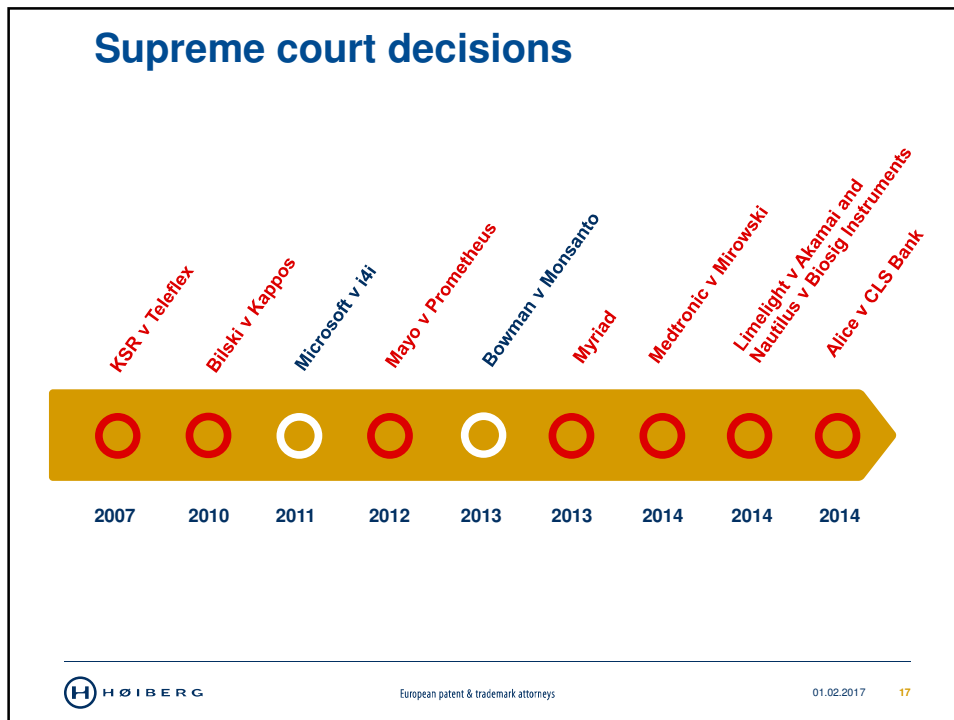


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Nobody has succeeded in isolating the compound

Amazonic acid background

Applicant has isolated amazonic acid

Has demonstrated effect in treatment of breast and colon cancer

Has created deoxy amazonic acid, with same activity as amazonic.

Amazonic acid

- Claim 1: Purified amazonic acid
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- Claim 3: A method of treating breast or colon cancer, comprising: administering an effective amount of purified amazonic acid to a patient suffering from breast or colon cancer.

Patentability Assessment

Claim 1 is not patentable. Separating the acid from its surrounding material in the leaf has resulted in the purified amazonic acid having not markedly different characteristics from its naturally occurring counterpart.

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Pomelo Juice

1. A composition comprising pomelo juice, and a an effective amount of a preservative.
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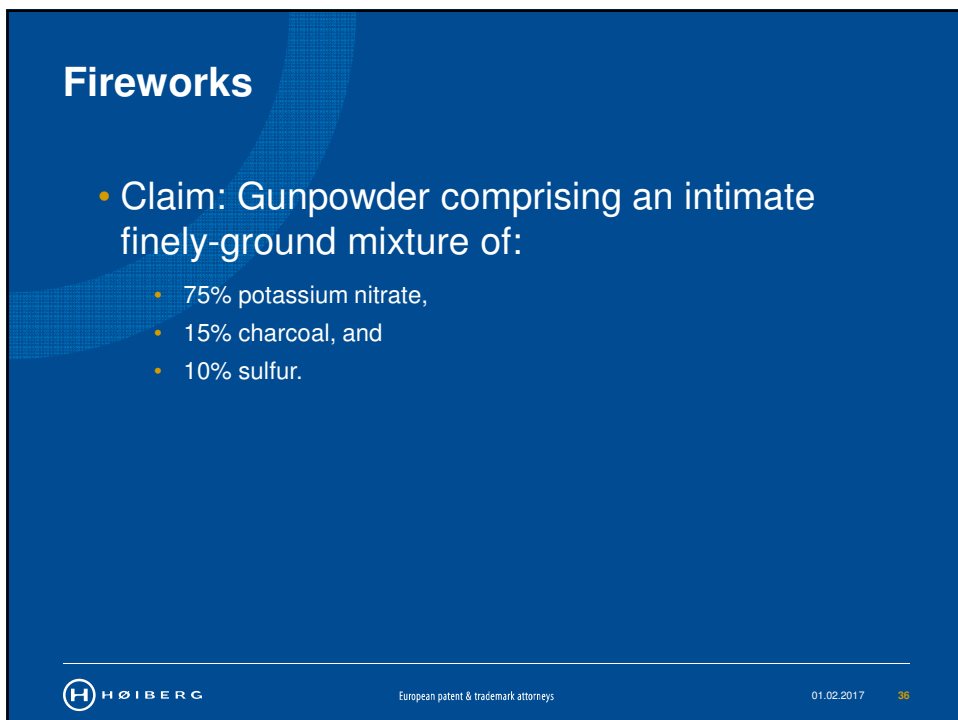
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Gunpowder

 HØIBERG European patent & trademark attorneys 01.02.2017 95



Fireworks

- Claim: Gunpowder comprising an intimate finely-ground mixture of:
 - 75% potassium nitrate,
 - 15% charcoal, and
 - 10% sulfur.

 HØIBERG European patent & trademark attorneys 01.02.2017 96

We have an Invention!

This claim is patentable.

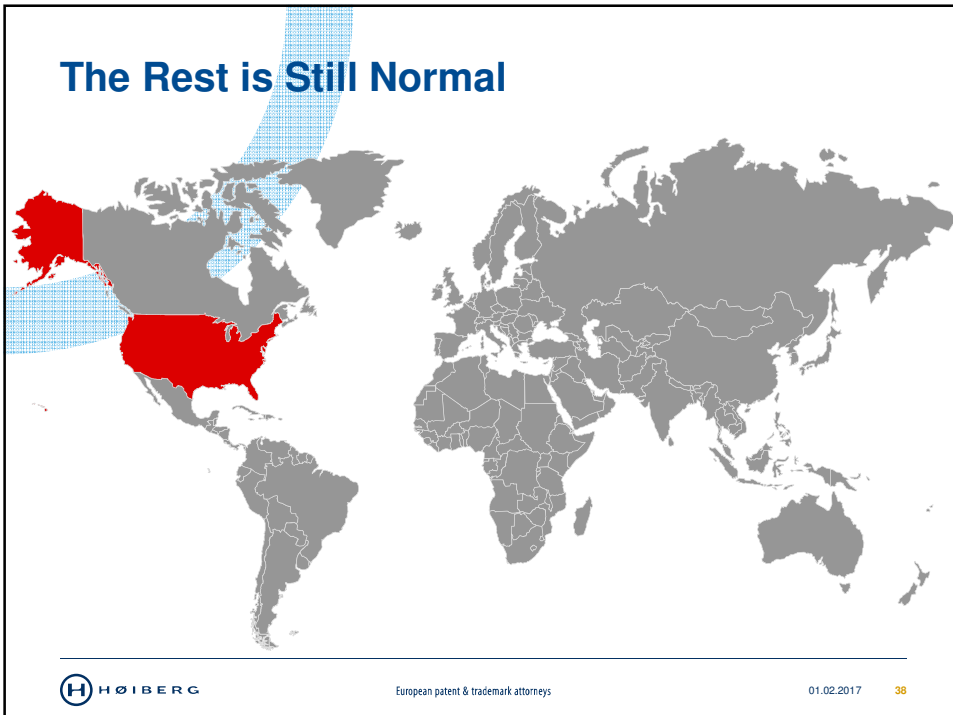
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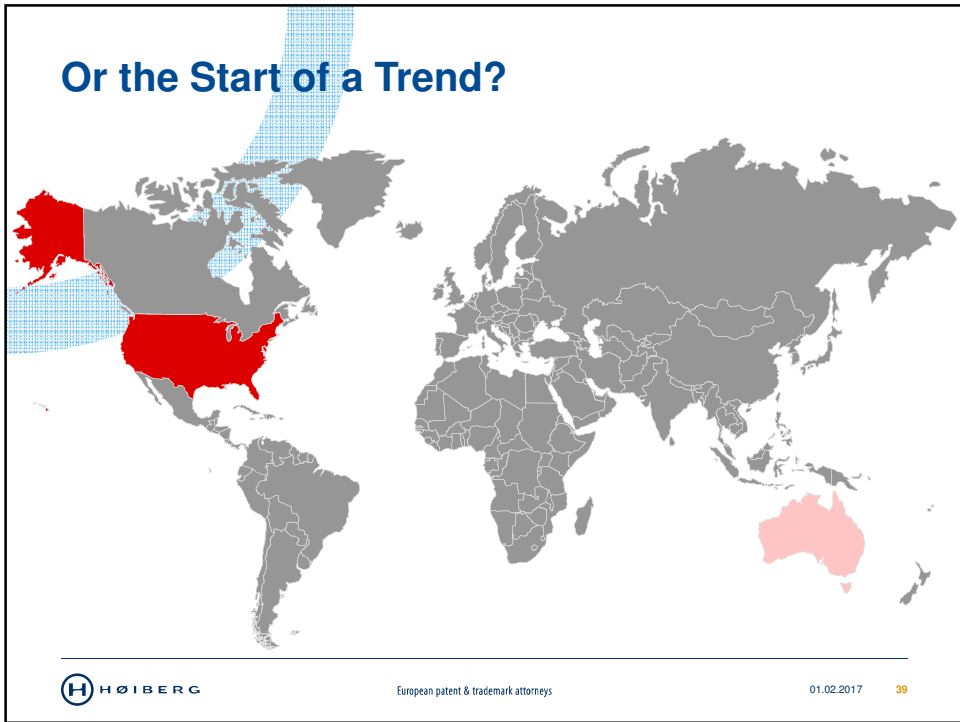
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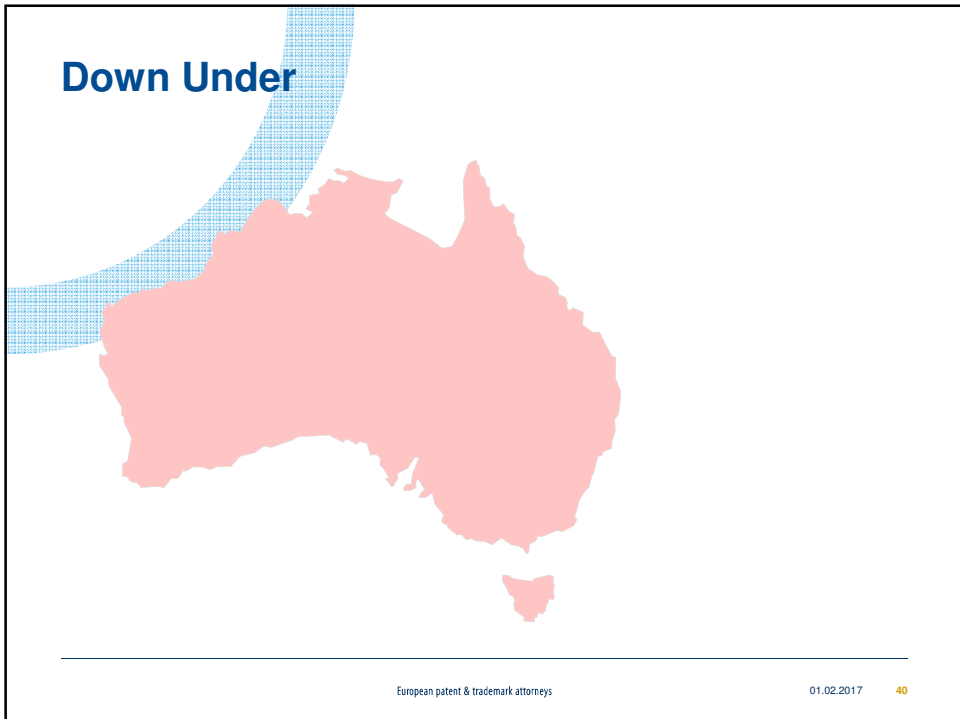
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European patent & trademark attorneys
01.02.2017 39

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European patent & trademark attorneys
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Recent Decision from AU High Court


- Myriad Genetic's Australian patent on BRCA1 and BRCA2 mutations.
- Claims to isolated DNA: not patentable
- Vectors, probes: patentable
- Diagnostic methods: patentable

Guidance from AU Patent Office

- Proteins and peptides are patentable
- Isolated small molecules (amazonic acid) are patentable
- Diagnostic methods are patentable
- Methods of treatment are patentable



Diagnostics


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Diagnostics

Focus on new and patentable analytical methods

Measure the marker using MS, HPLC or similar "high tech"

Recite all steps of analytical method (e.g. PCR, Elisa)

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Diagnosis

Tie the diagnostic method to treatment, follow-on diagnostics

e.g. add a method of treatment step at the end (if tested positive for condition X, treat with drug Y)

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Compound patents

Compound patents

Add synthesis claims – recombinant or synthetic

Add mutant/derivative/conjugate claims

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Other Exceptions in General

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- Computer programs "as such"

India

- No patents on plants, seeds, or animals
- No patents on drug formulations
- No patents on salts
- No patents on new use of known compound
- No patents on products isolated from nature

**Thank you
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Exceptions to Patentability

What cannot be done

Jens Viktor Nørgaard
01.02.2017

 HØIBERG European patent & trademark attorneys

Speaker / CV



Jens Viktor Nørgaard

Head of Biotechnology & Plant sciences
Partner, European Patent Attorney, PhD,
MSc, Royal Veterinary and Agricultural
University of Copenhagen

jvn@hoiberg.com

 HØIBERG European patent & trademark attorneys 01.02.2017

Agenda

Stem cells
Plant varieties
Products of nature
Laws of nature
Abstract ideas

Why Exceptions



- Ethics, morale
- Non-technical
- Alternative types of protection
- Courts' interpretation of the law
- Public/lobbyist pressure

East meets West

USA

Common law country

Governed by

- the law
- Court interpretation

Europe

Legislator decides

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Stem cells (European Exemption)

- The law:
- No patents on:
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- Board of Appeal of EPO, German Courts and European Court of Justice have decided that an embryo encompasses a fertilised human egg, i.e. a stem cell
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Plant Varieties

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European patent & trademark attorneys
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Plant Varieties - Background

New plant varieties can be Protected (UPOV; CPVO)

European exception

Breeder's & farmer's privilege

H HØIBERG
European patent & trademark attorneys
01.02.2017 10

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Plant Varieties – European Status

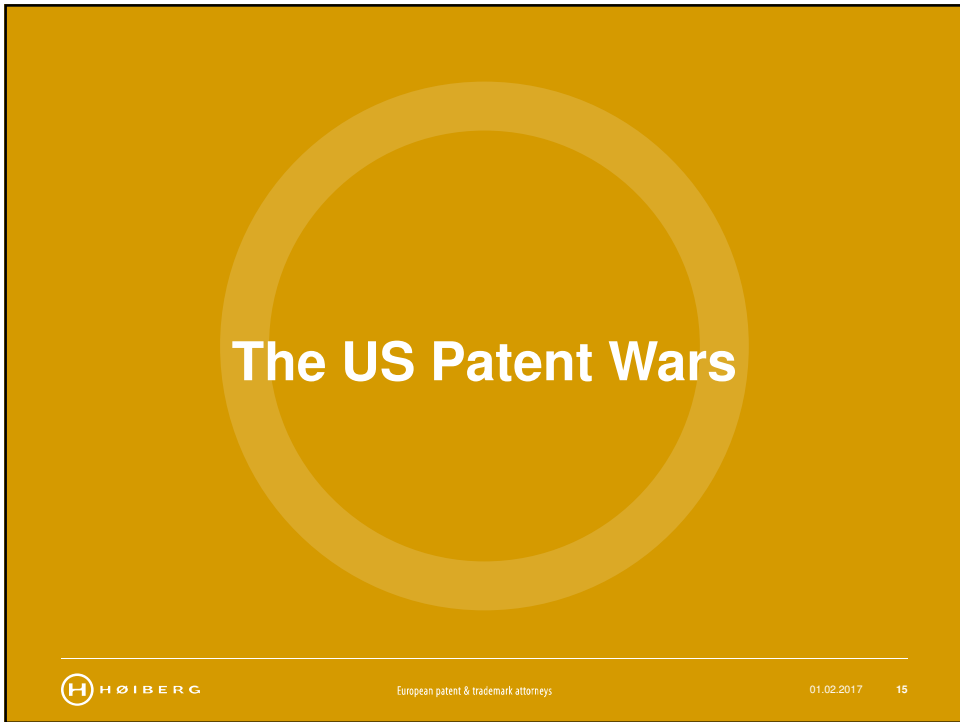
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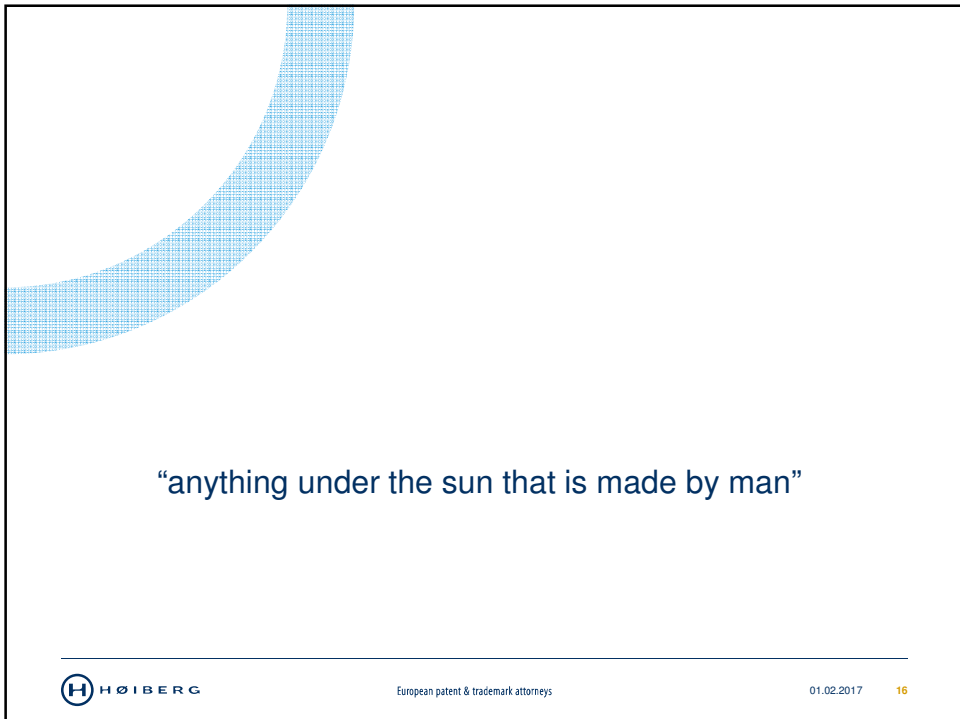
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The US Patent Wars

 HØIBERG European patent & trademark attorneys 01.02.2017 15

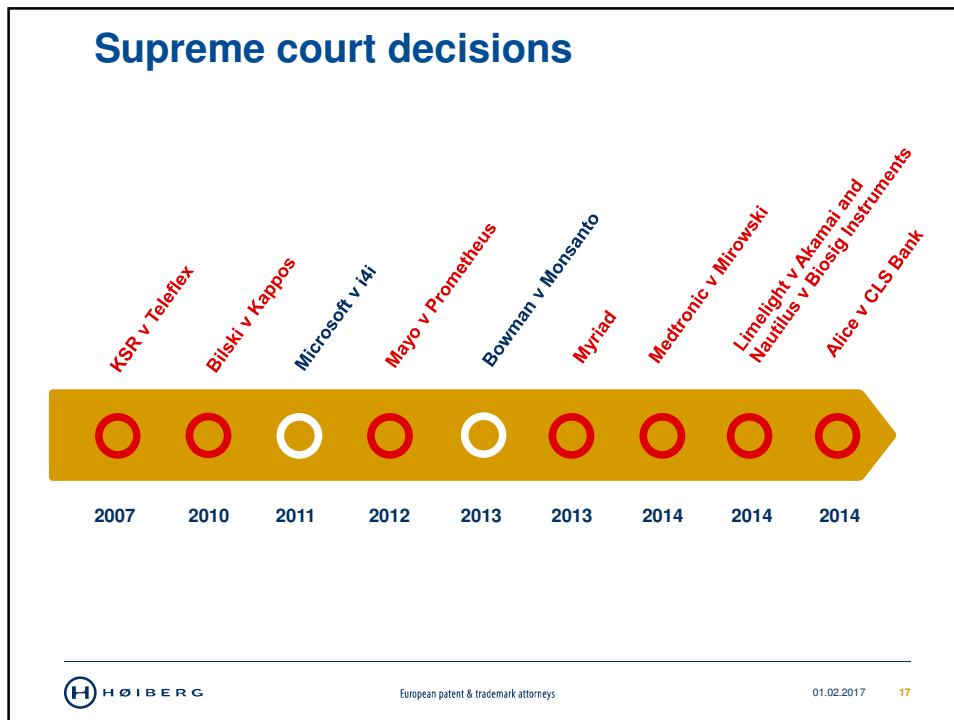
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 HØIBERG European patent & trademark attorneys 01.02.2017 16

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What does the law say

Patent eligible subject matter (§ 101):
 Whoever invents or discovers any new and useful
process,
machine,
manufacture, or
composition of matter, or
 any new and useful improvement thereof, may obtain a patent
 therefor, subject to the conditions and requirements of this title.


European patent & trademark attorneys
01.02.2017
18

Mayo vs. Prometheus

- Prometheus Labs had rights to a series of US patents directed to a diagnostic method.
- The method involved:
 - Determining the level of metabolites of thiopurines
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Mayo vs. Prometheus


Patent protection
is a two-edged
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Provides incentives
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There is a danger
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Consequences

- No diagnostic patents are granted
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 HØIBERG European patent & trademark attorneys 01.02.2017 21

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 HØIBERG European patent & trademark attorneys 01.02.2017 22

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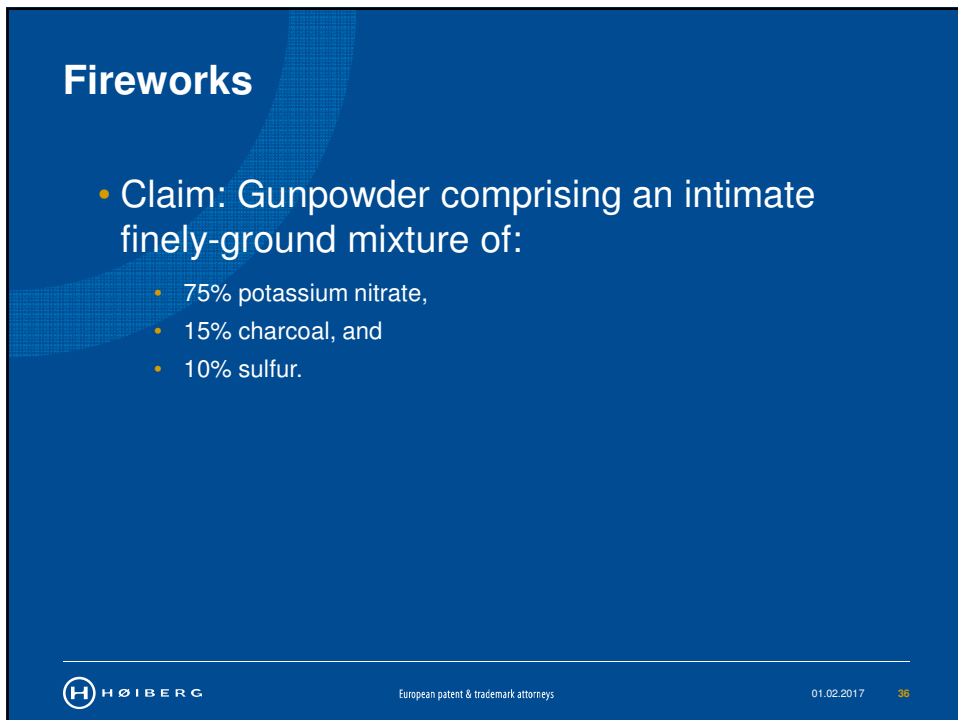
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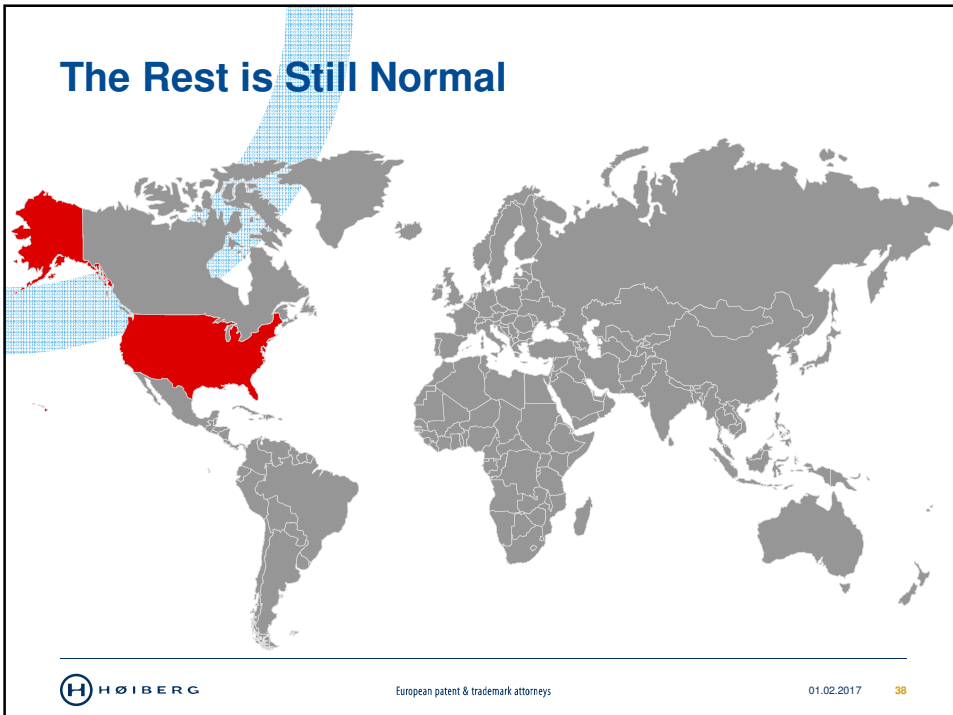
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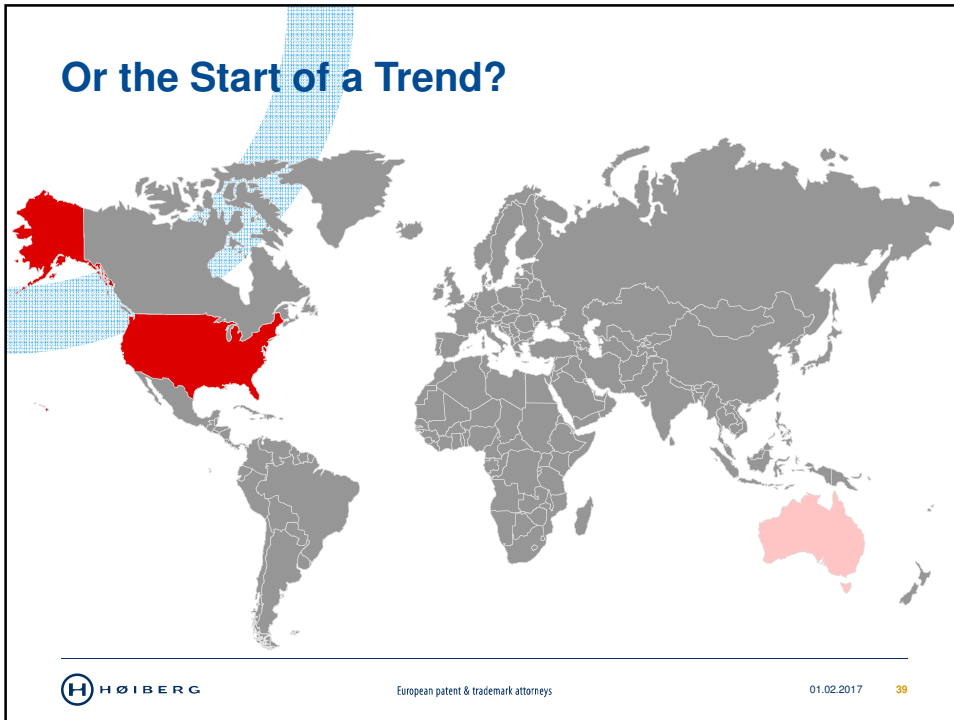
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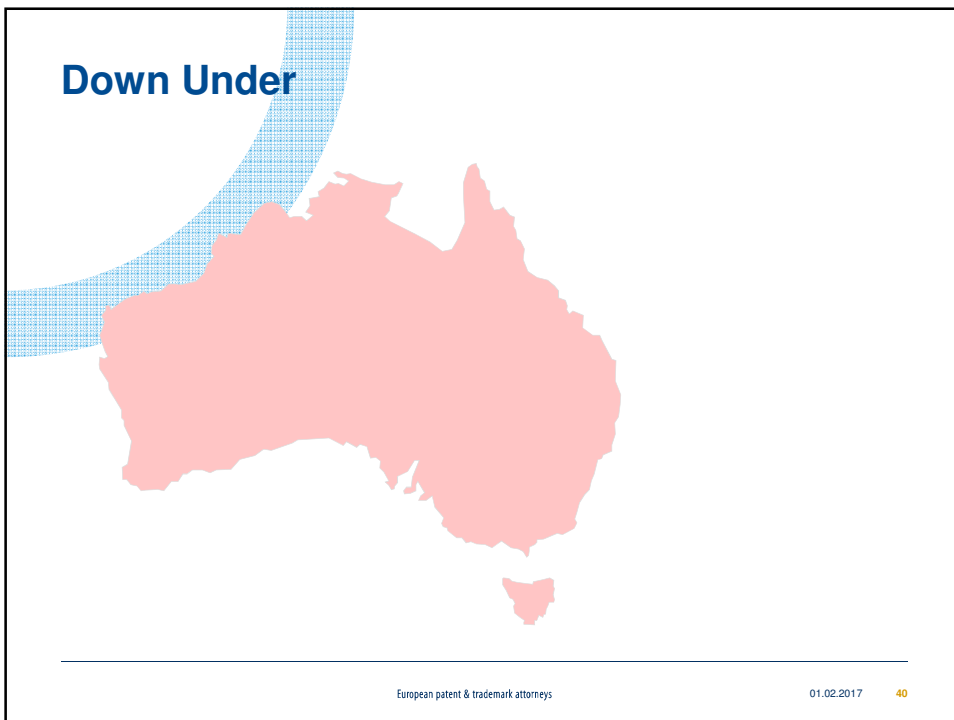
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European patent & trademark attorneys

01.02.2017 39

Down Under



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European patent & trademark attorneys

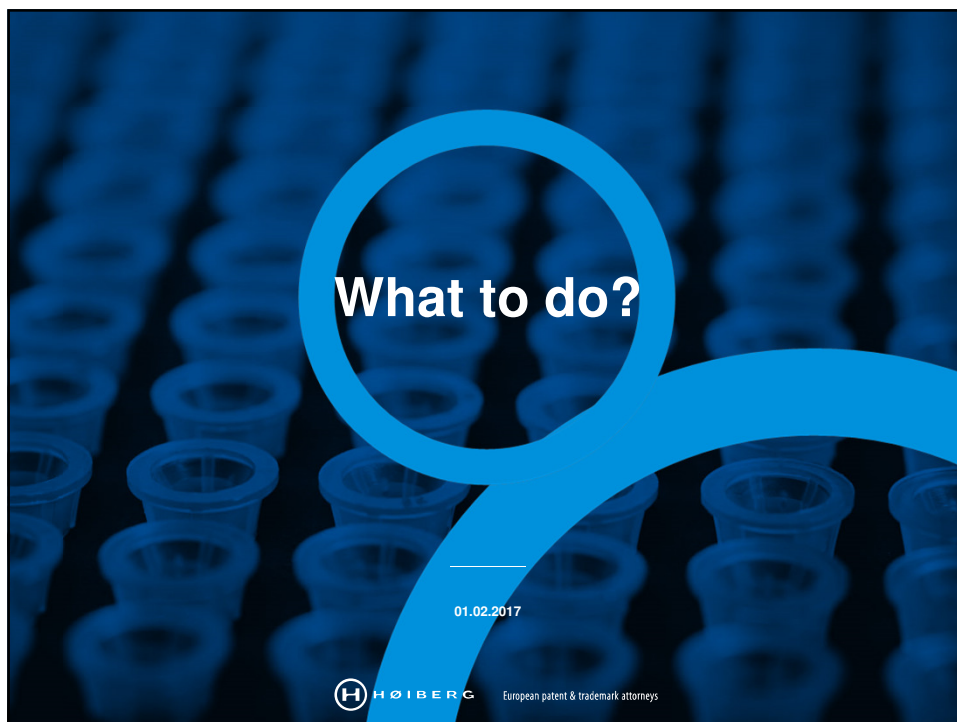
01.02.2017 40

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Diagnostics


 HØIBERG European patent & trademark attorneys 01.02.2017 45

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What cannot be done

Jens Viktor Nørgaard
01.02.2017

 HØIBERG European patent & trademark attorneys

Speaker / CV



Jens Viktor Nørgaard

Head of Biotechnology & Plant sciences
Partner, European Patent Attorney, PhD,
MSc, Royal Veterinary and Agricultural
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jvn@hoiberg.com

 HØIBERG European patent & trademark attorneys 01.02.2017

Agenda

Stem cells
Plant varieties
Products of nature
Laws of nature
Abstract ideas

Why Exceptions



- Ethics, morale
- Non-technical
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Plant Varieties

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European patent & trademark attorneys
01.02.2017 9

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Plant Varieties - Background

New plant varieties can be Protected (UPOV; CPVO)

European exception

Breeder's & farmer's privilege

H HØIBERG
European patent & trademark attorneys
01.02.2017 10

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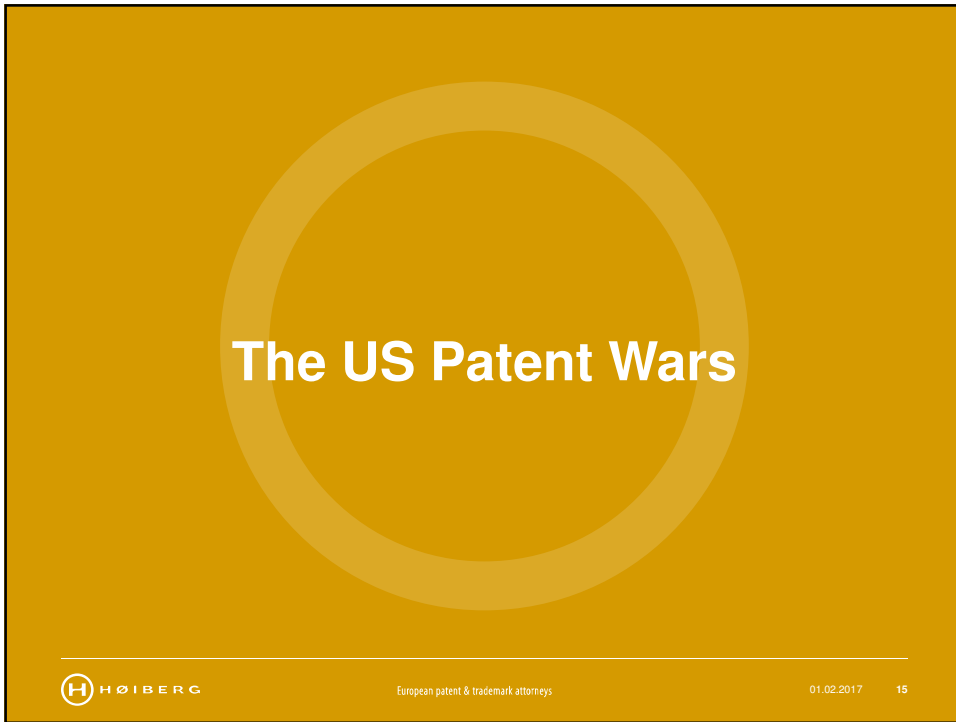
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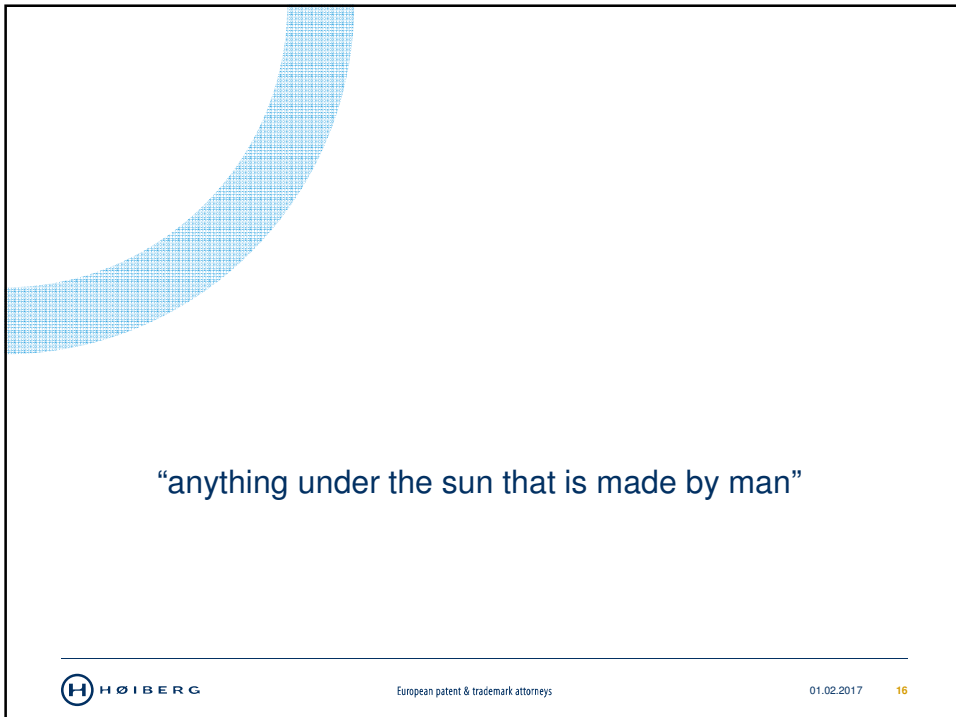
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The US Patent Wars

 HØIBERG European patent & trademark attorneys 01.02.2017 15

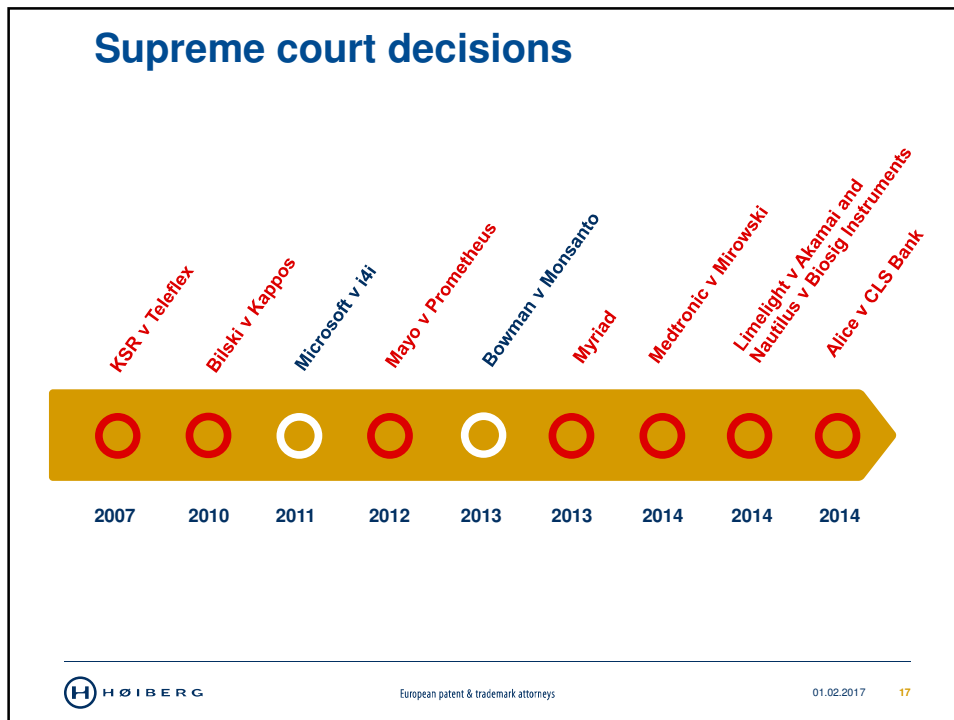
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H Ø I B E R G European patent & trademark attorneys 01.02.2017 18

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 HØIBERG European patent & trademark attorneys 01.02.2017 21

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 HØIBERG European patent & trademark attorneys 01.02.2017 22

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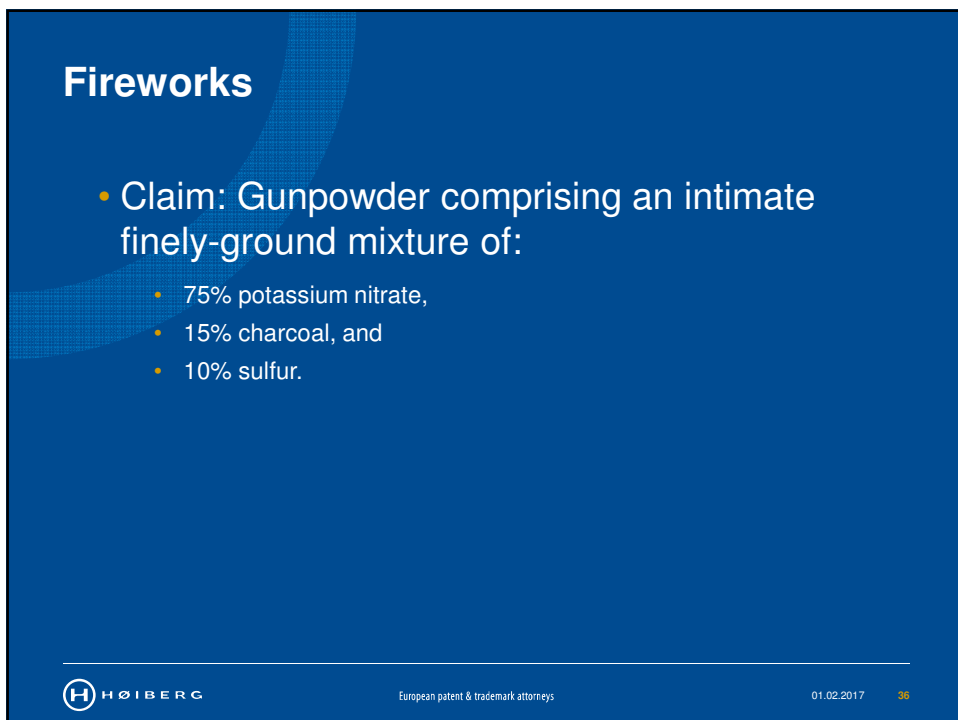
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 HØIBERG European patent & trademark attorneys 01.02.2017 95



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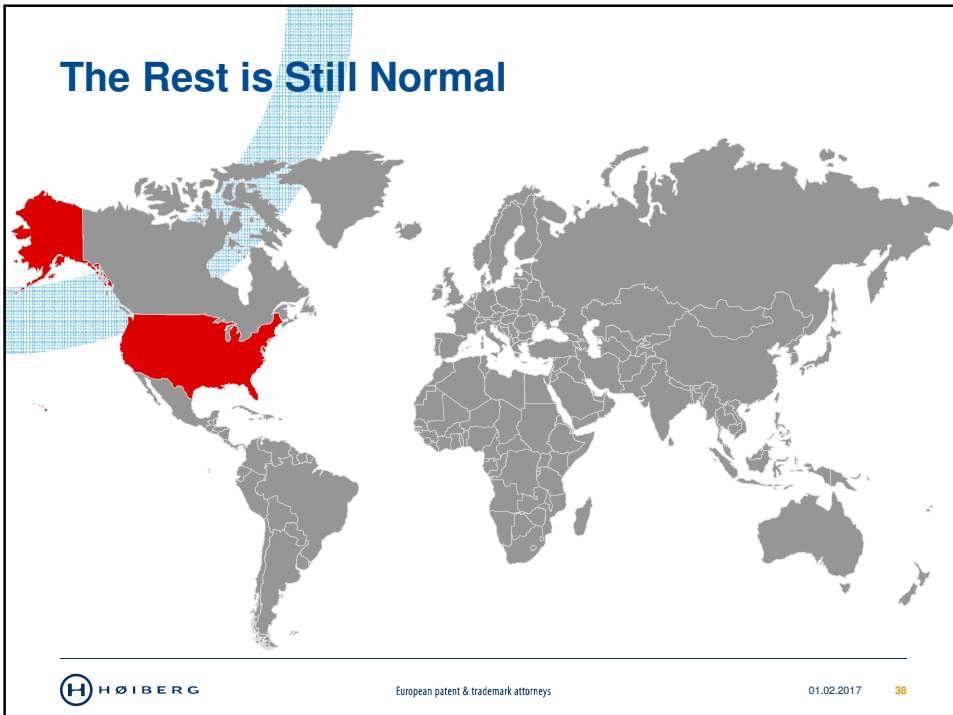
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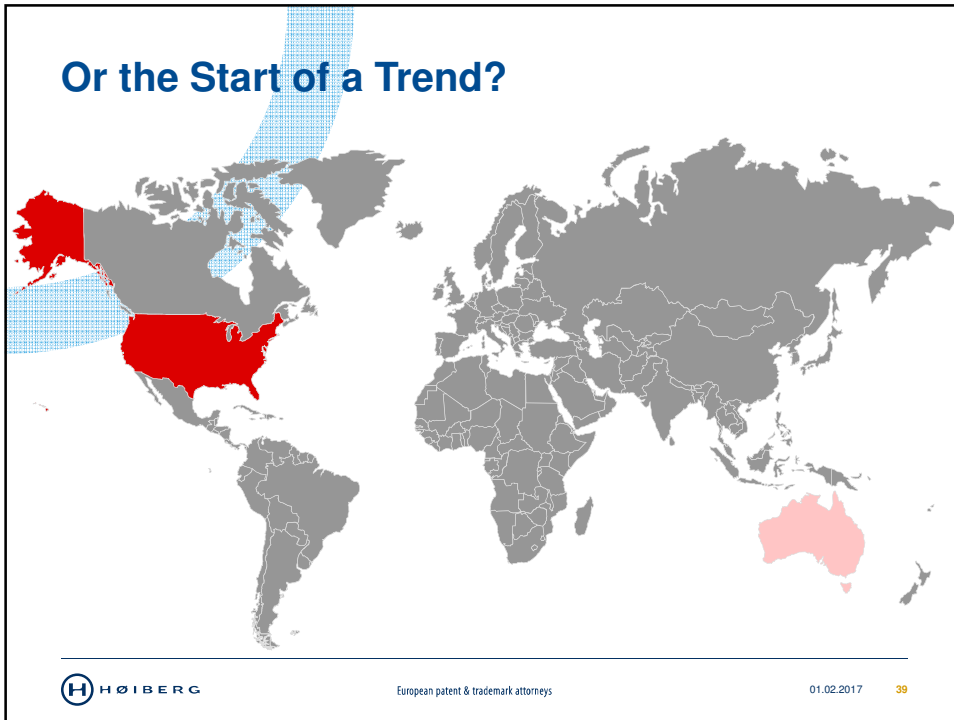
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The Rest is Still Normal



Or the Start of a Trend?



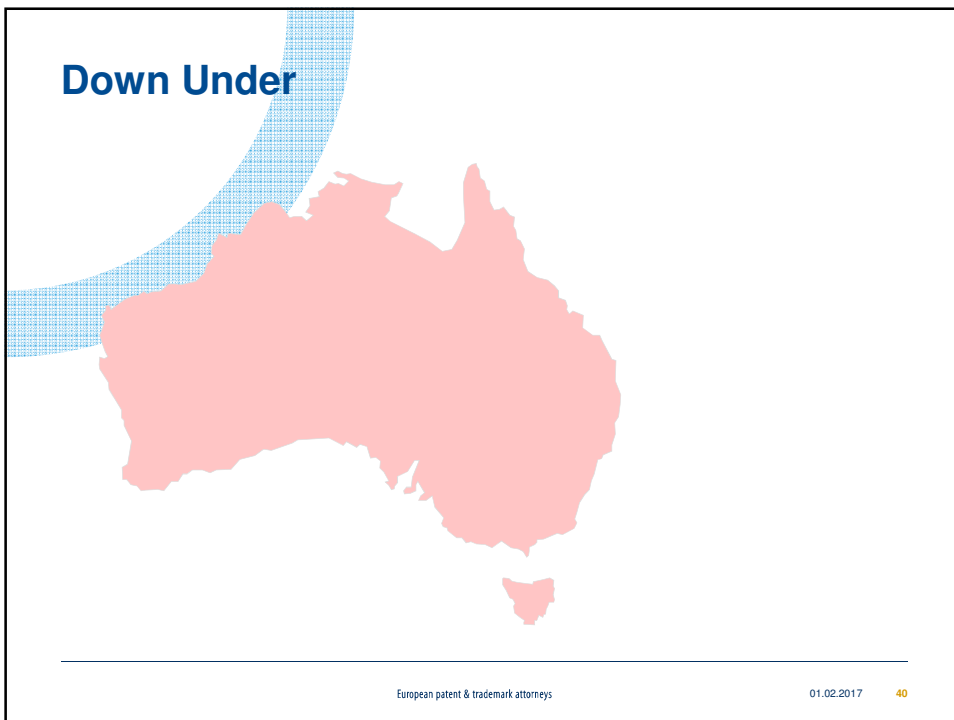
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Recent Decision from AU High Court


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- Claims to isolated DNA: not patentable
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Guidance from AU Patent Office

- Proteins and peptides are patentable
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Diagnostics


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Diagnostics

Focus on new and patentable analytical methods

Measure the marker using MS, HPLC or similar "high tech"

Recite all steps of analytical method (e.g. PCR, Elisa)

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Tie the diagnostic method to treatment, follow-on diagnostics

e.g. add a method of treatment step at the end (if tested positive for condition X, treat with drug Y)

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Add synthesis claims – recombinant or synthetic

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Other Exceptions in General

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- No patents on plants, seeds, or animals
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**Thank you
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Exceptions to Patentability

What cannot be done

Jens Viktor Nørgaard
01.02.2017

 HØIBERG European patent & trademark attorneys

Speaker / CV



Jens Viktor Nørgaard

Head of Biotechnology & Plant sciences
Partner, European Patent Attorney, PhD,
MSc, Royal Veterinary and Agricultural
University of Copenhagen

jvn@hoiberg.com

 HØIBERG European patent & trademark attorneys 01.02.2017

Agenda

Stem cells
Plant varieties
Products of nature
Laws of nature
Abstract ideas

Why Exceptions



- Ethics, morale
- Non-technical
- Alternative types of protection
- Courts' interpretation of the law
- Public/lobbyist pressure

East meets West

USA

Common law country

Governed by

- the law
- Court interpretation

Europe

Legislator decides

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Stem cells (European Exemption)

- The law:
- No patents on:
 - Processes for cloning human beings
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Stem Cells

- Board of Appeal of EPO, German Courts and European Court of Justice have decided that an embryo encompasses a fertilised human egg, i.e. a stem cell
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European patent & trademark attorneys
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New plant varieties can be Protected (UPOV; CPVO)

European exception

Breeder's & farmer's privilege

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European patent & trademark attorneys
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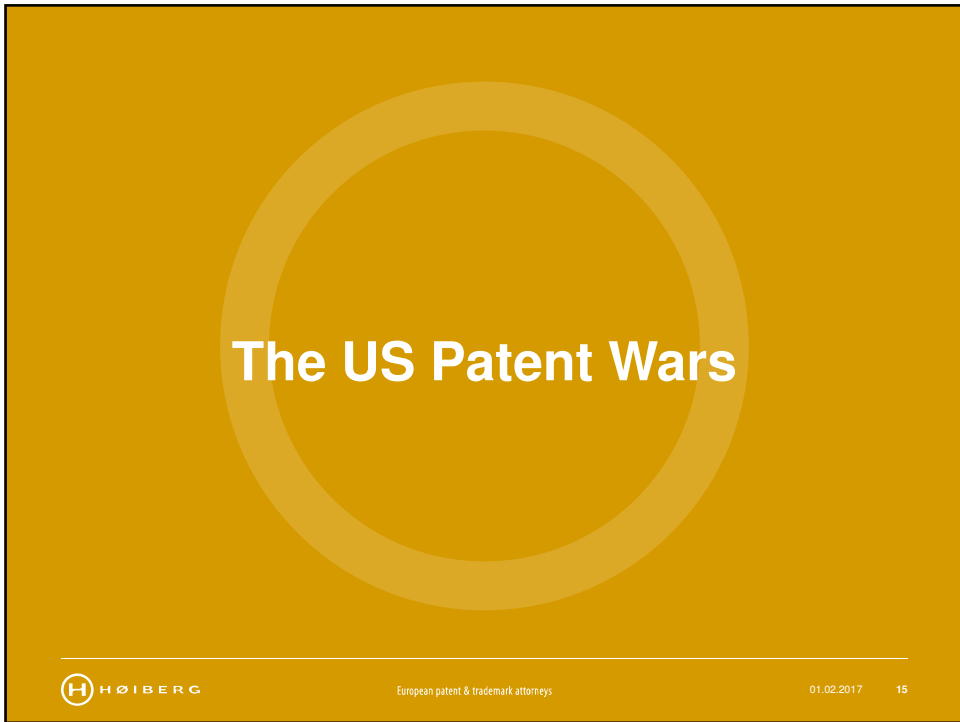
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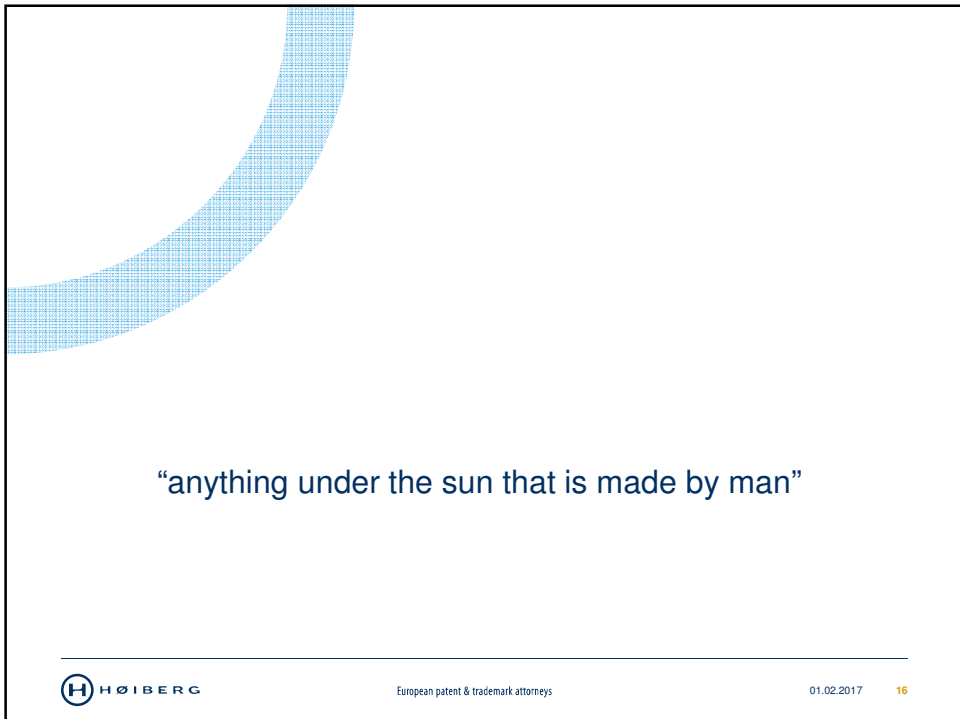
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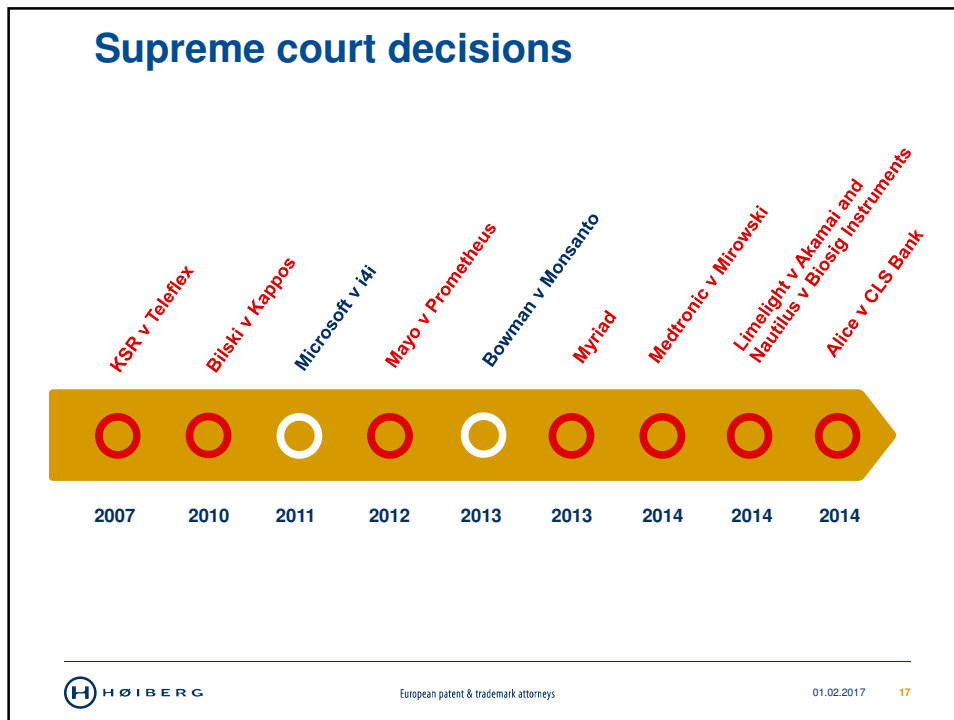
The US Patent Wars

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“anything under the sun that is made by man”

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What does the law say

Patent eligible subject matter (§ 101):
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H Ø I B E R G European patent & trademark attorneys 01.02.2017 18

Mayo vs. Prometheus

- Prometheus Labs had rights to a series of US patents directed to a diagnostic method.
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 - Determining the level of metabolites of thiopurines
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There is a danger
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- It is important to note what is *not* implicated by this decision.
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Examples from Guidelines and Training materials

- Amazonic acid (anticancer drug from plant)
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Amazonic acid background

Amazonian cherry tree grows wild in Amazonas

It's leaves contain a substance that has anti-cancer effects

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Applicant has isolated amazonic acid

Has demonstrated effect in treatment of breast and colon cancer

Has created deoxy amazonic acid, with same activity as amazonic.

Amazonic acid

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1. A composition comprising pomelo juice, and a an effective amount of a preservative.
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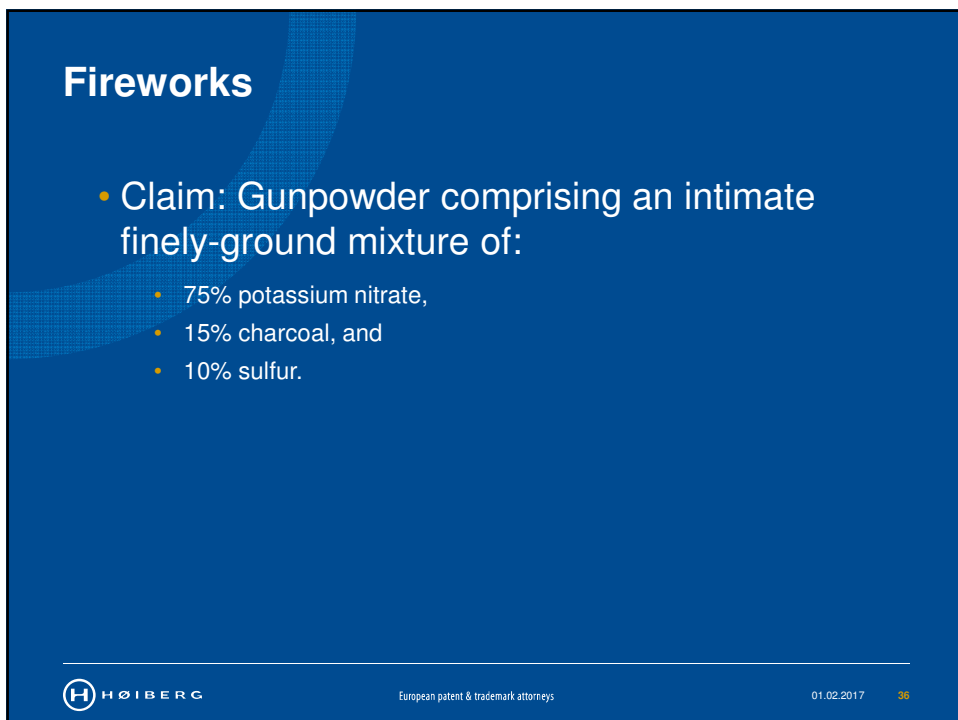


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- Claim: Gunpowder comprising an intimate finely-ground mixture of:
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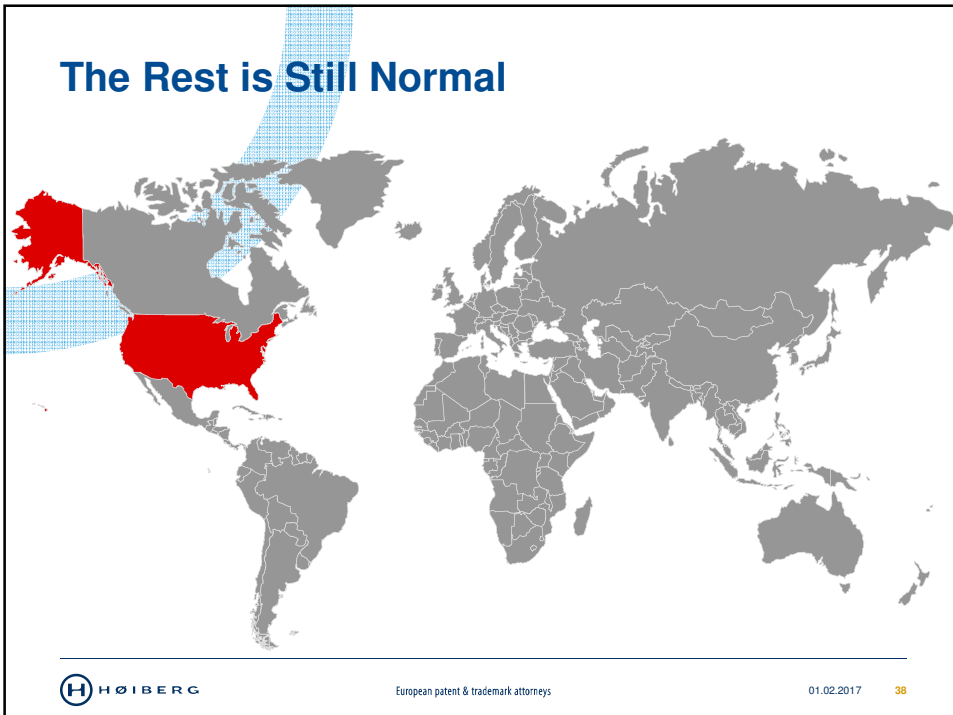
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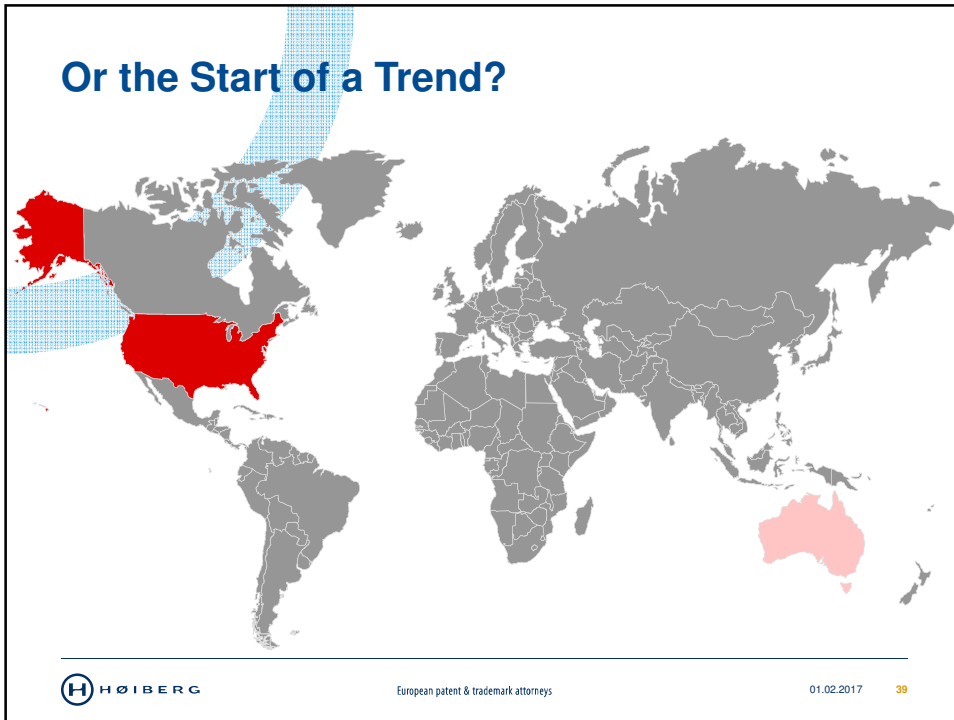
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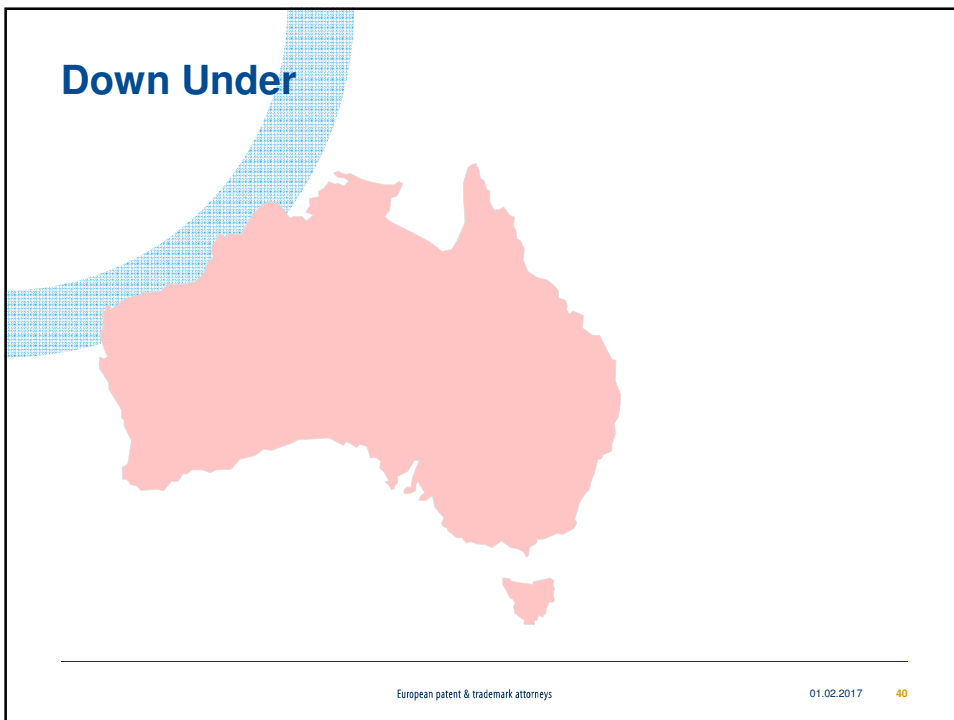
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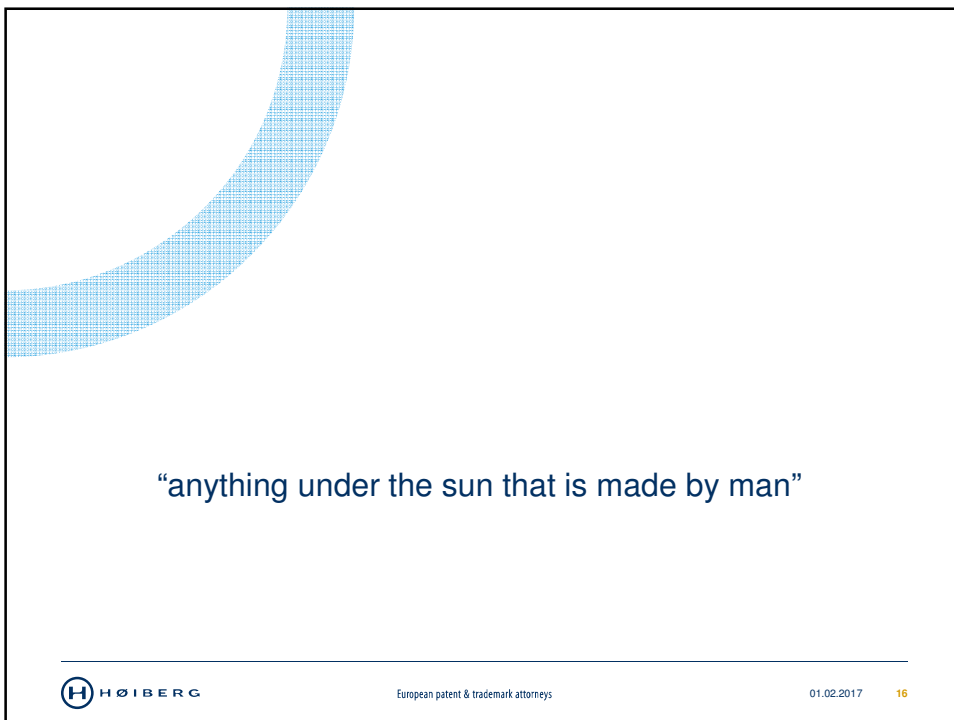
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The US Patent Wars

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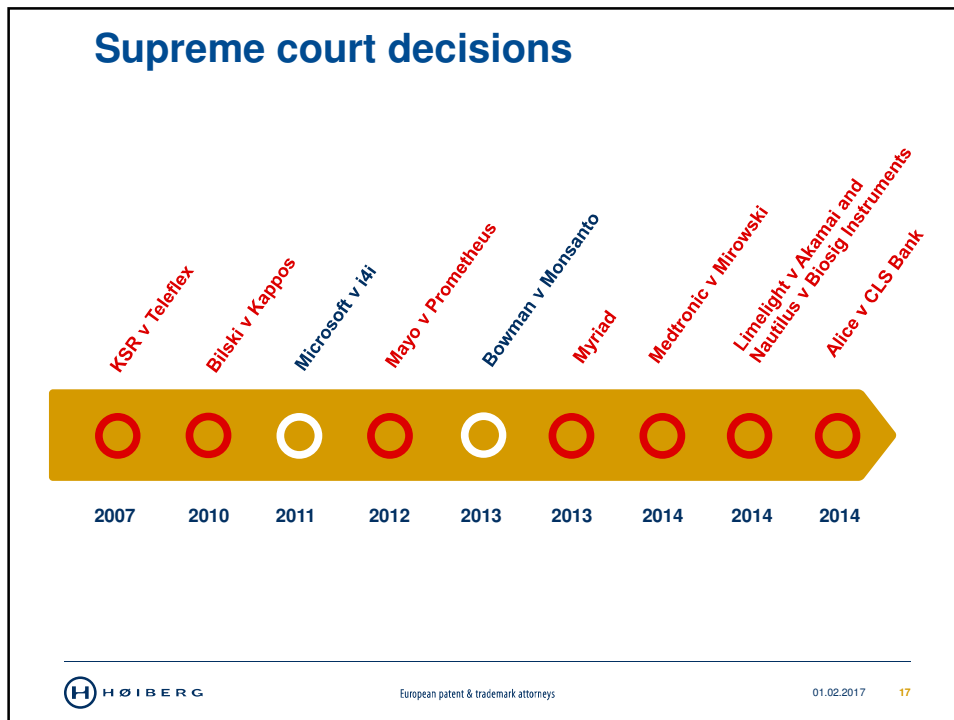
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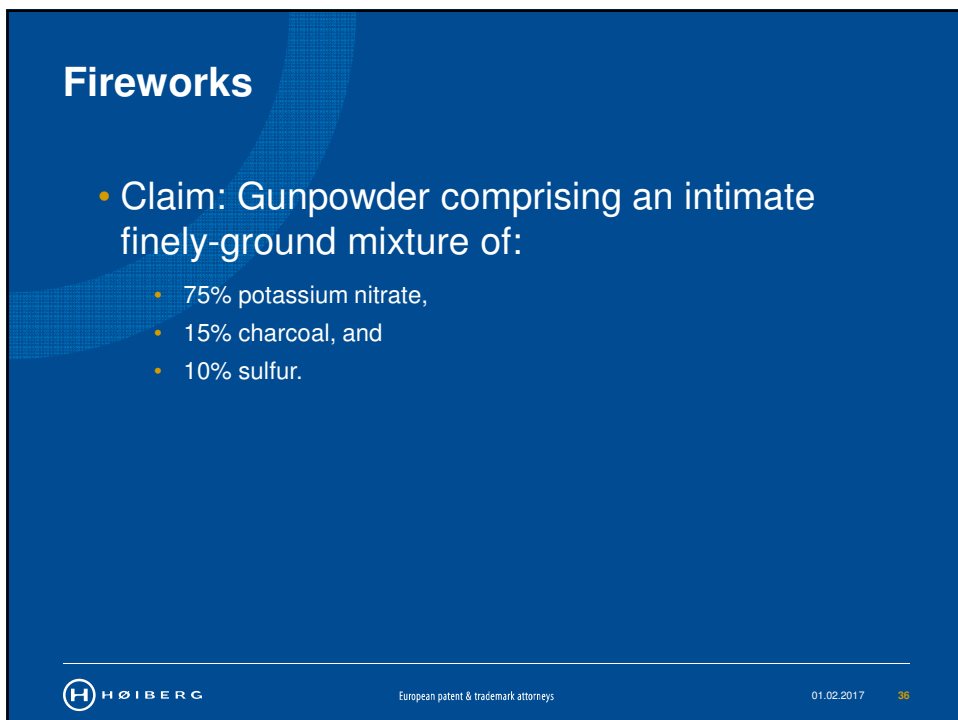


Gunpowder

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European patent & trademark attorneys

01.02.2017 95



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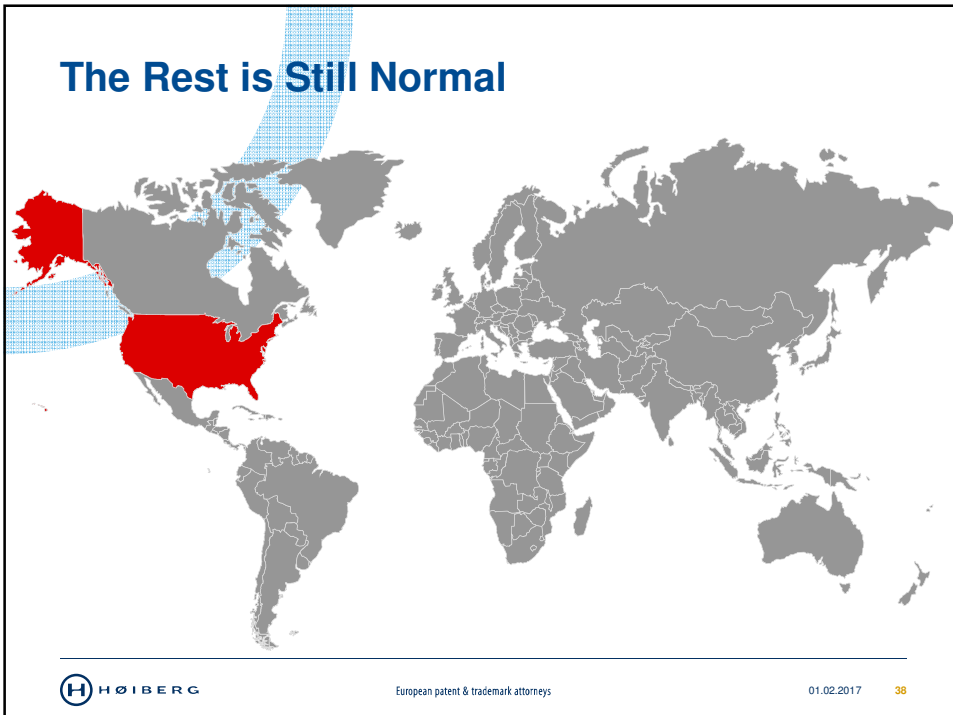
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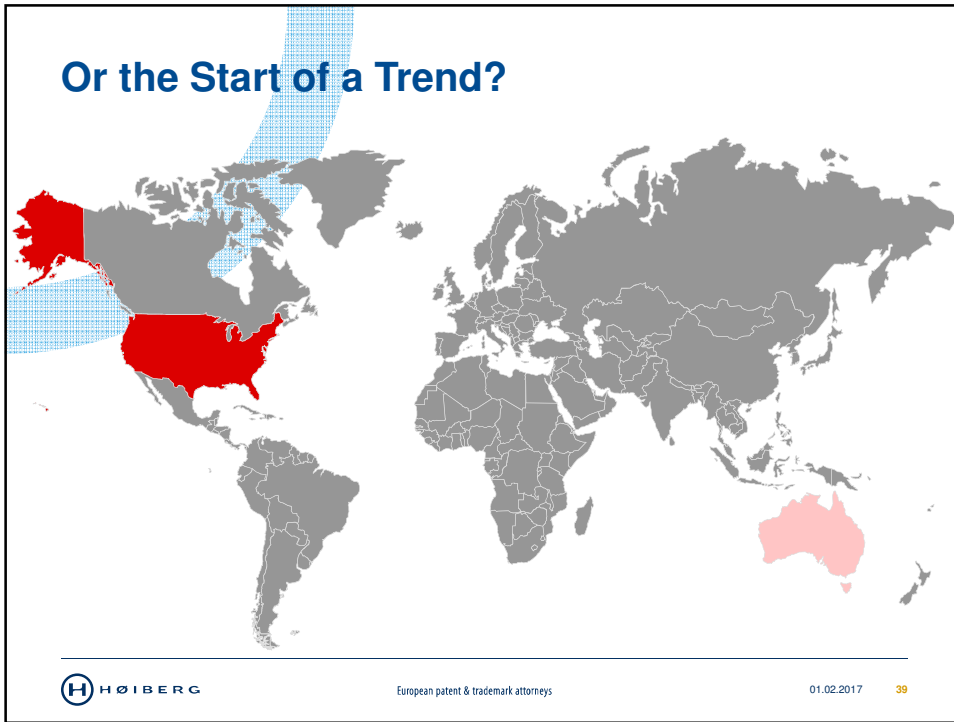
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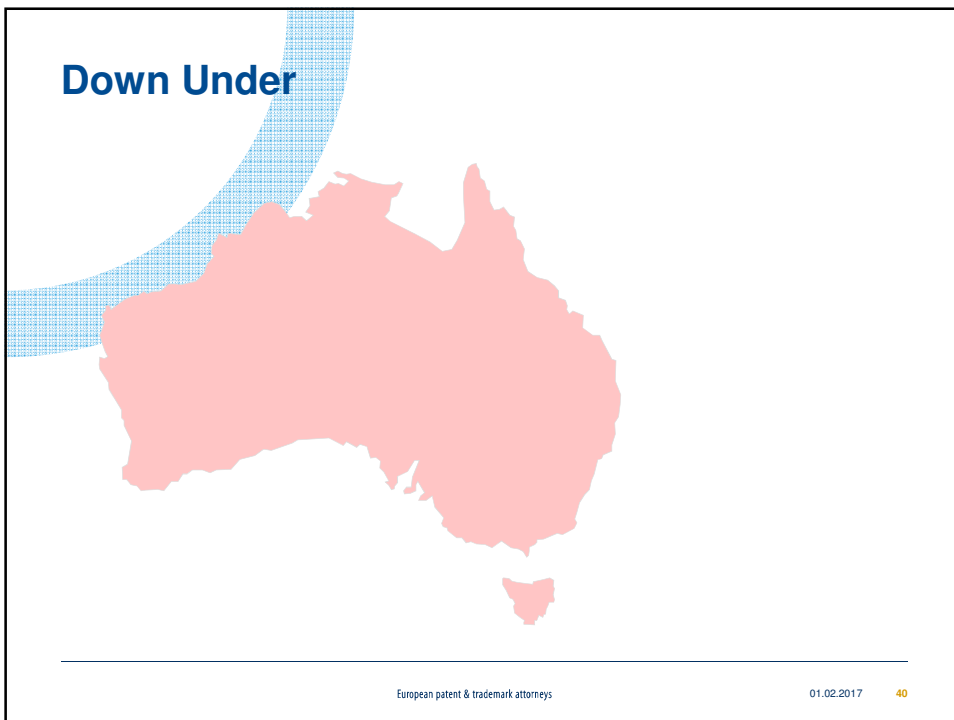
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 HØIBERG European patent & trademark attorneys 01.02.2017 4

East meets West

USA

Common law country

Governed by

- the law
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Europe

Legislator decides

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Stem cells (European Exemption)

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Plant Varieties

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Plant Varieties - Background

New plant varieties can be Protected (UPOV; CPVO)

European exception

Breeder's & farmer's privilege

H HØIBERG European patent & trademark attorneys 01.02.2017 10

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- Patents are not granted on plant and animal varieties.
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Plant Varieties – European Status

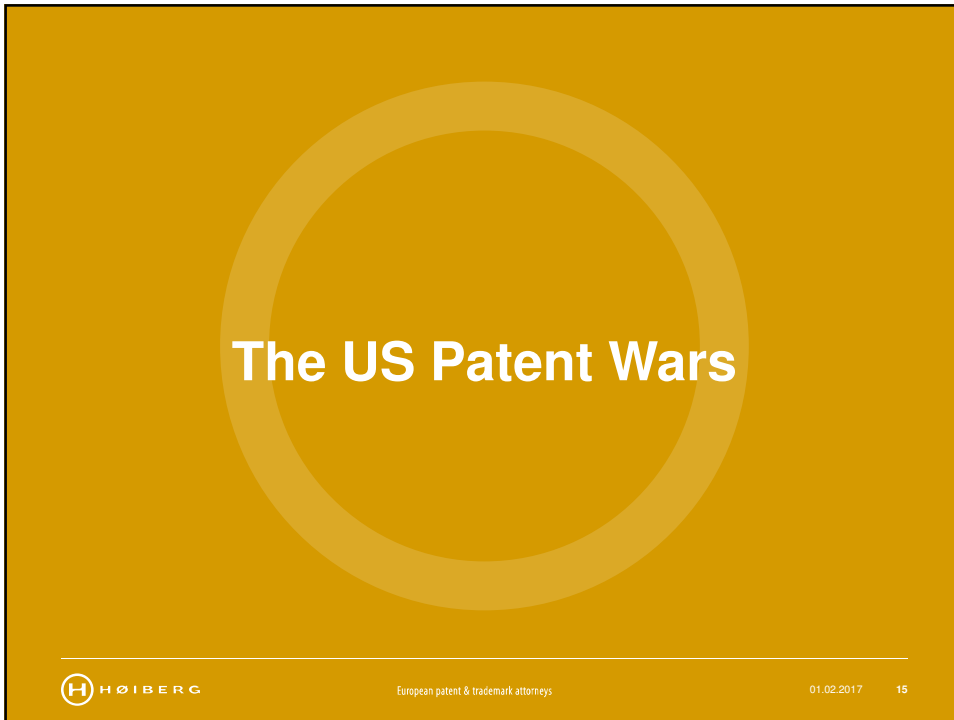
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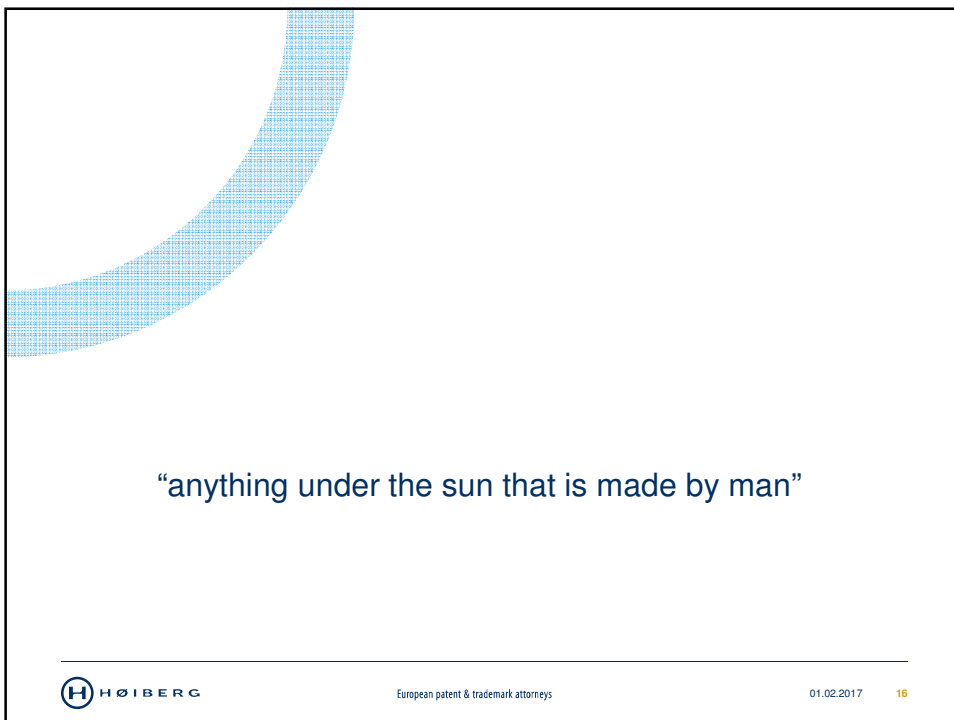
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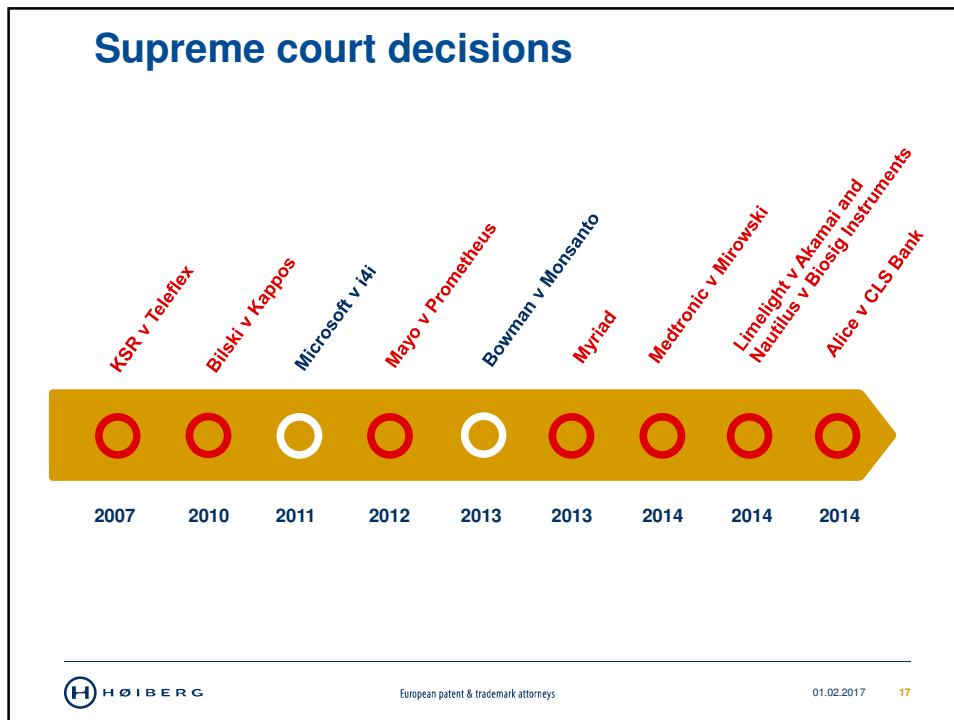
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 HØIBERG European patent & trademark attorneys 01.02.2017 15



“anything under the sun that is made by man”

 HØIBERG European patent & trademark attorneys 01.02.2017 16



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Patent eligible subject matter (§ 101):
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Mayo vs. Prometheus

- Prometheus Labs had rights to a series of US patents directed to a diagnostic method.
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 HØIBERG European patent & trademark attorneys 01.02.2017 21

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- Myriad Genetics proprietor to a number of US patents
- Patent claims:
 - "isolated" human deoxyribonucleic acid (DNA) sequences "BRCA1" and "BRCA2"; and
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 HØIBERG European patent & trademark attorneys 01.02.2017 22

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- It is important to note what is *not* implicated by this decision.
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Amazonic acid background

Amazonian cherry tree grows wild in Amazonas

It's leaves contain a substance that has anti-cancer effects

Nobody has succeeded in isolating the compound

Amazonic acid background

Applicant has isolated amazonic acid

Has demonstrated effect in treatment of breast and colon cancer

Has created deoxy amazonic acid, with same activity as amazonic.

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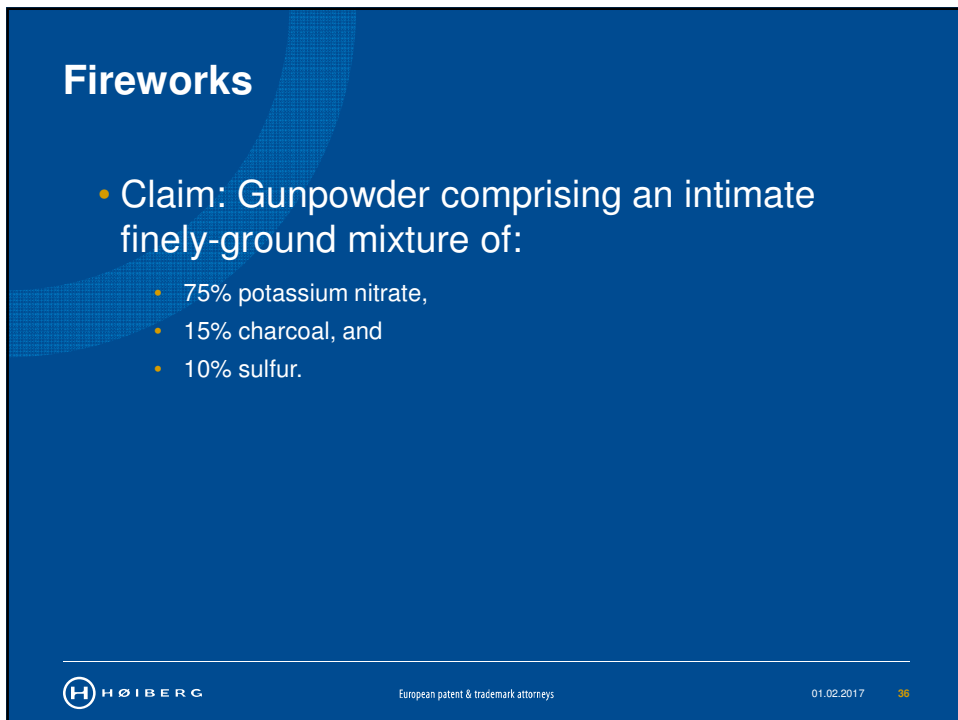
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 HØIBERG European patent & trademark attorneys 01.02.2017 95



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- Claim: Gunpowder comprising an intimate finely-ground mixture of:
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We have an Invention!

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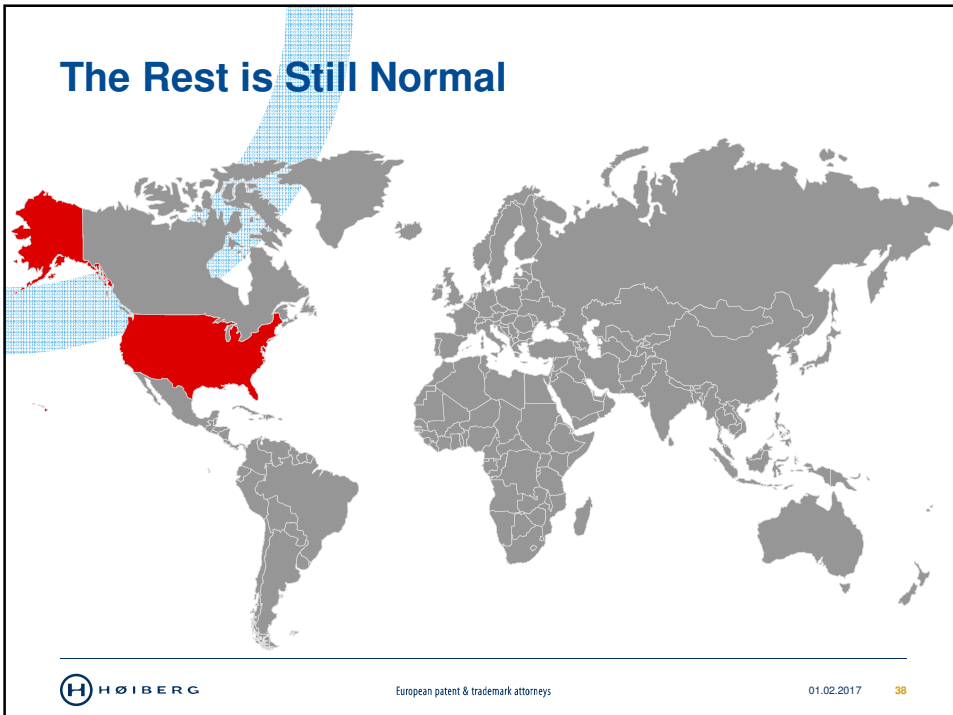
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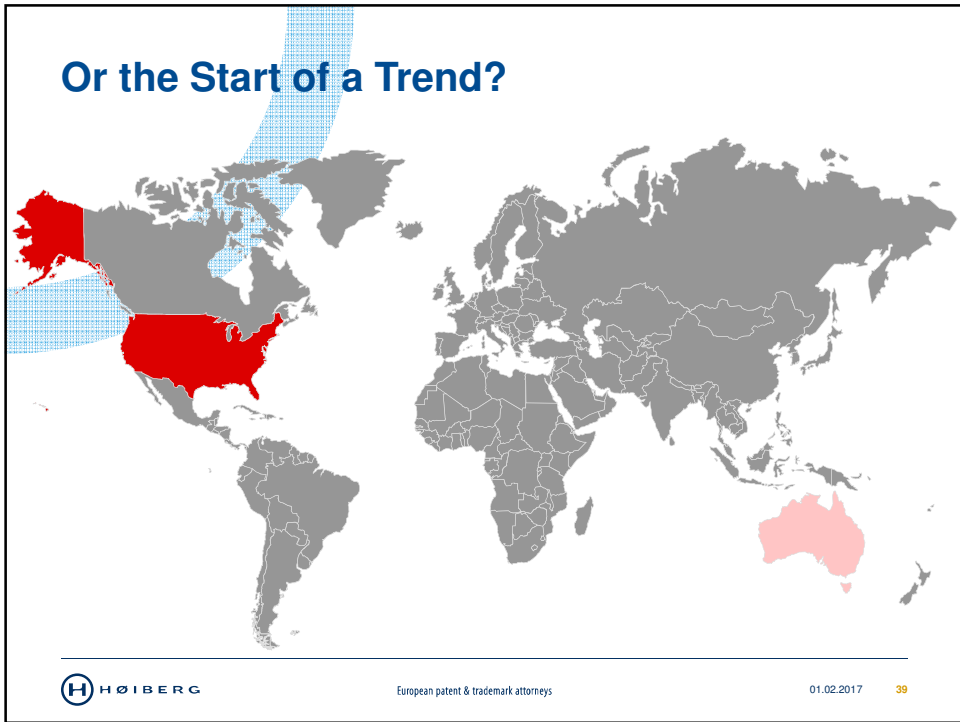
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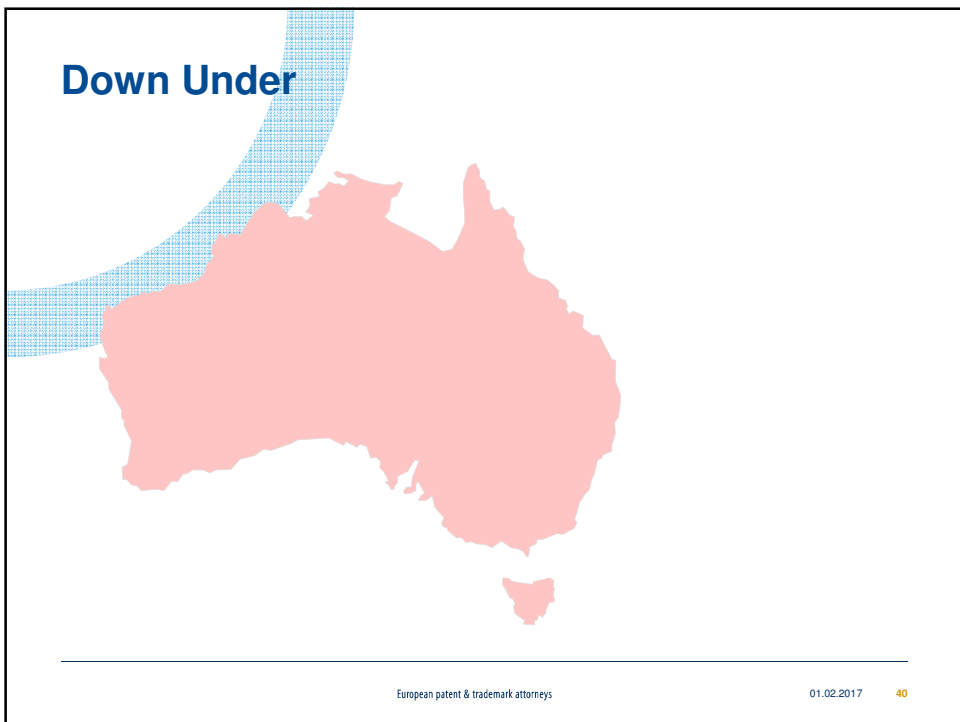
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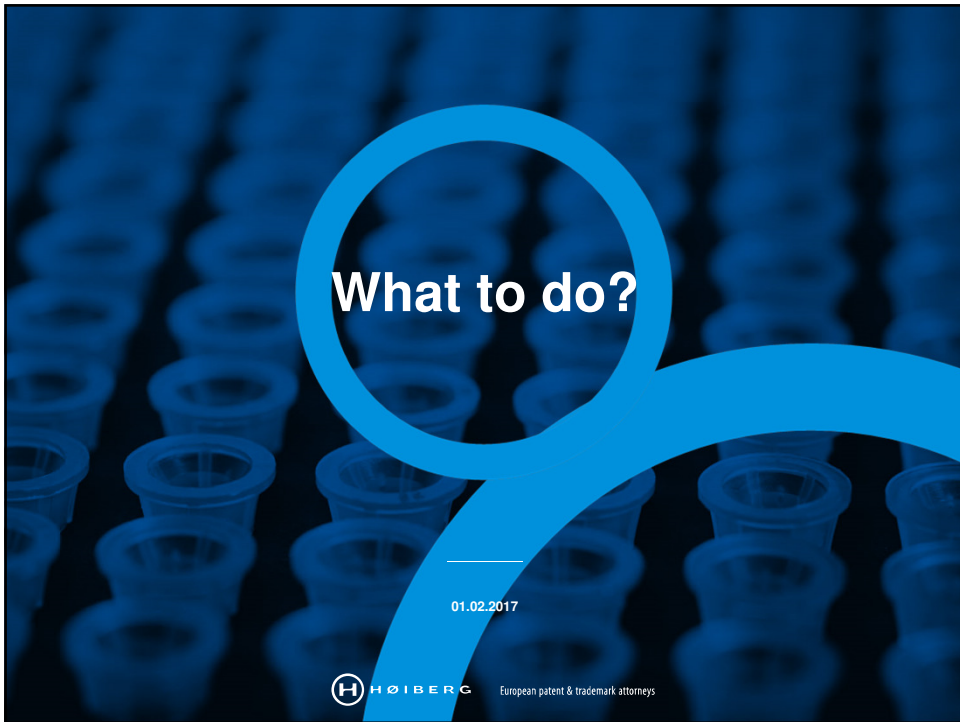
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- Proteins and peptides are patentable
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- Diagnostic methods are patentable
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Diagnostics


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Focus on new and patentable analytical methods

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Recite all steps of analytical method (e.g. PCR, Elisa)

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- No patents on plants, seeds, or animals
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Exceptions to Patentability

What cannot be done

Jens Viktor Nørgaard
01.02.2017

 HØIBERG European patent & trademark attorneys

Speaker / CV



Jens Viktor Nørgaard

Head of Biotechnology & Plant sciences
Partner, European Patent Attorney, PhD,
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jvn@hoiberg.com

 HØIBERG European patent & trademark attorneys 01.02.2017

Agenda

Stem cells
Plant varieties
Products of nature
Laws of nature
Abstract ideas

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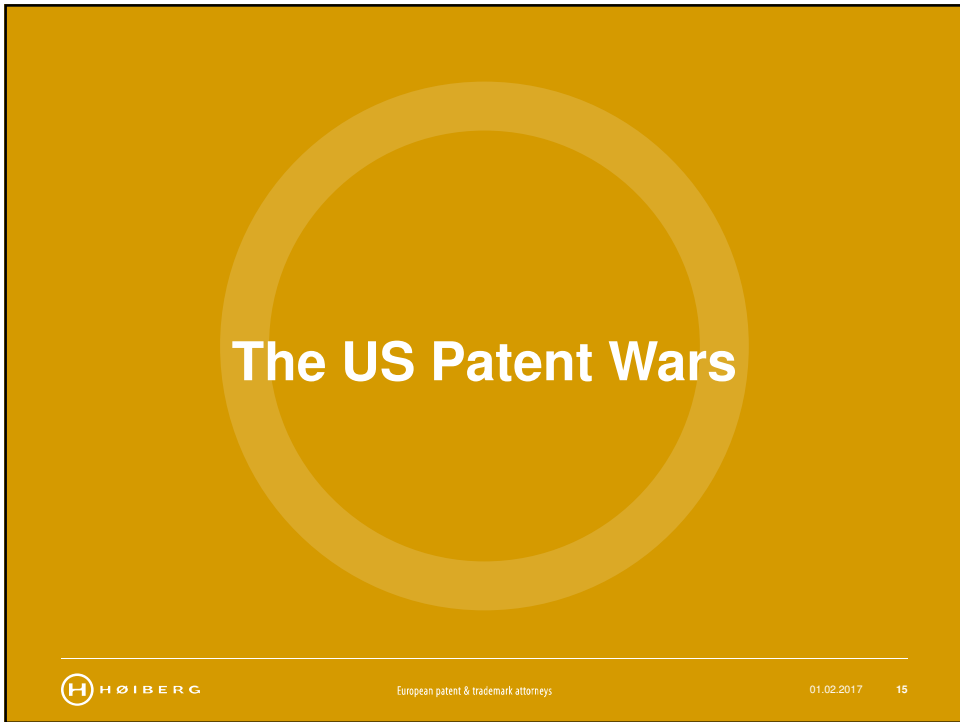
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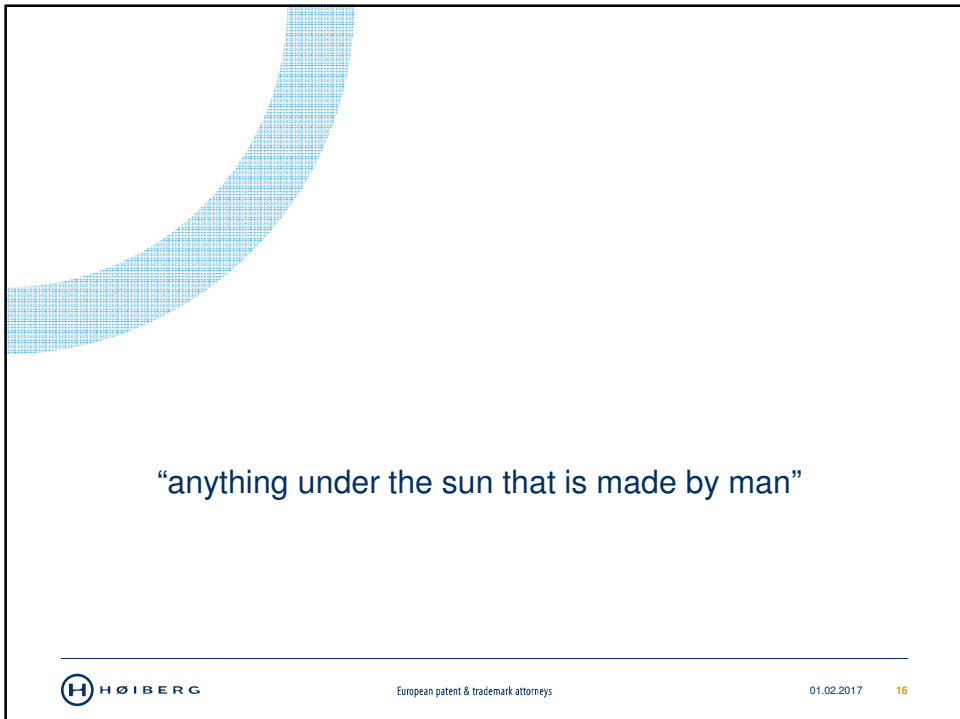
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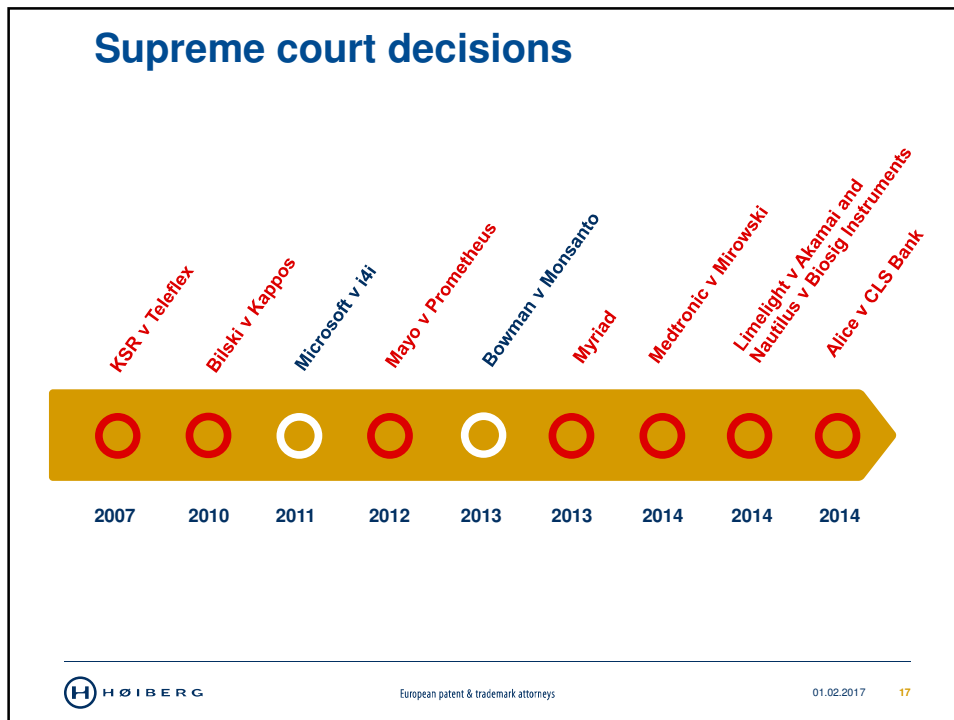
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H Ø I B E R G European patent & trademark attorneys 01.02.2017 18

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 HØIBERG European patent & trademark attorneys 01.02.2017 21

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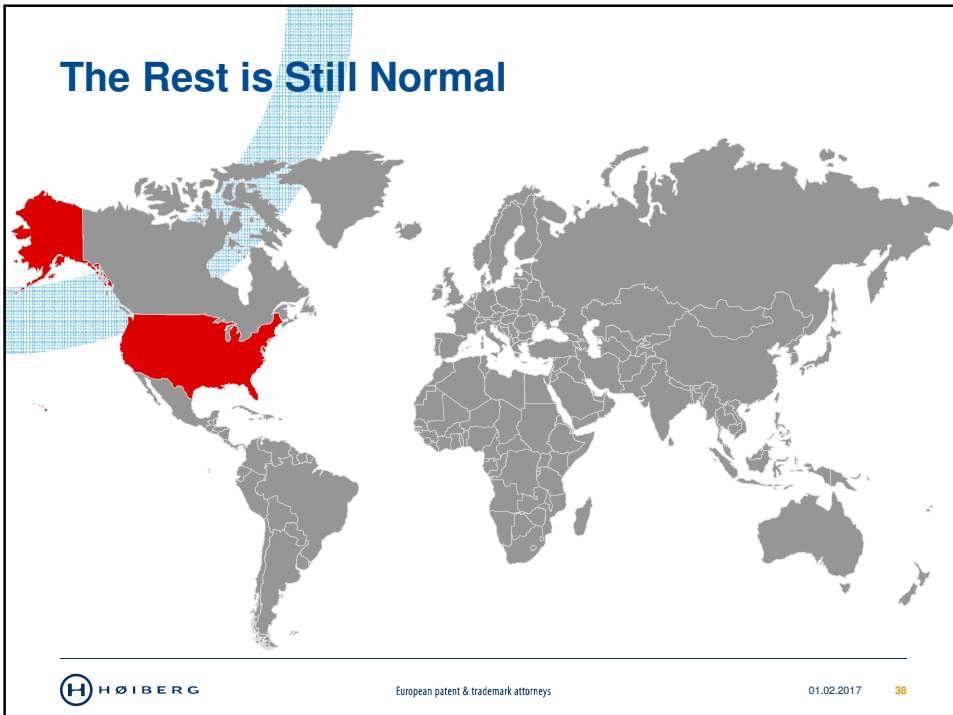
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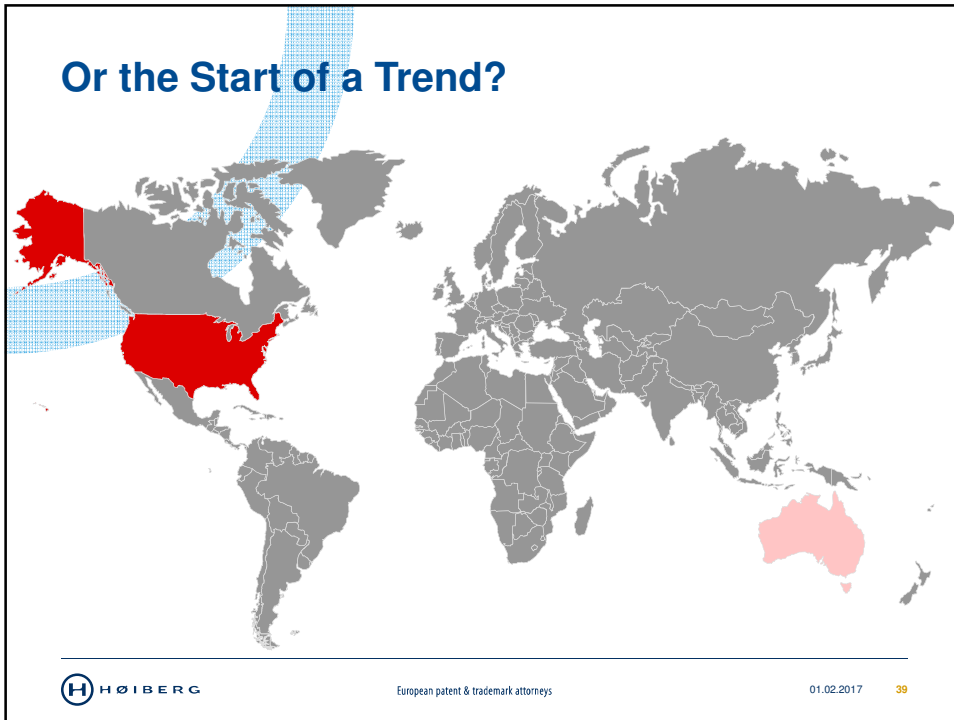
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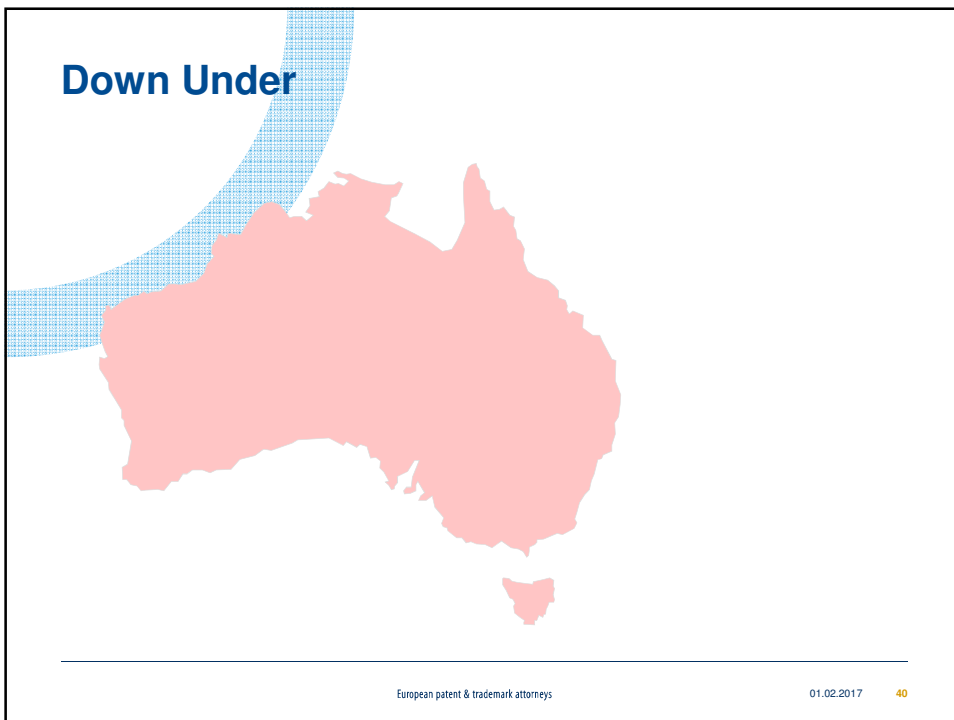
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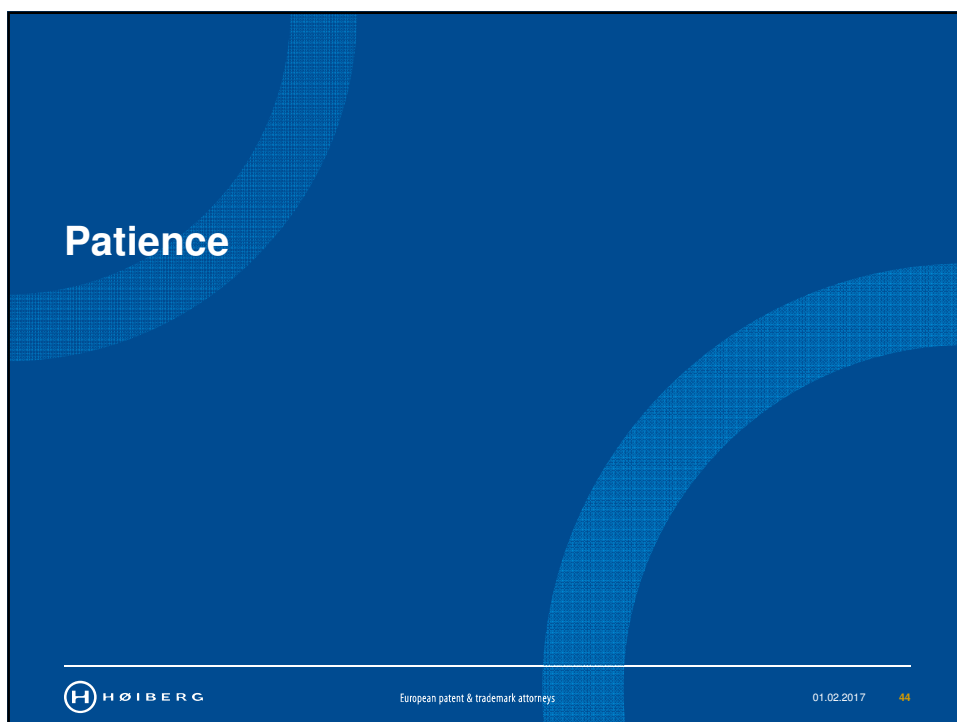
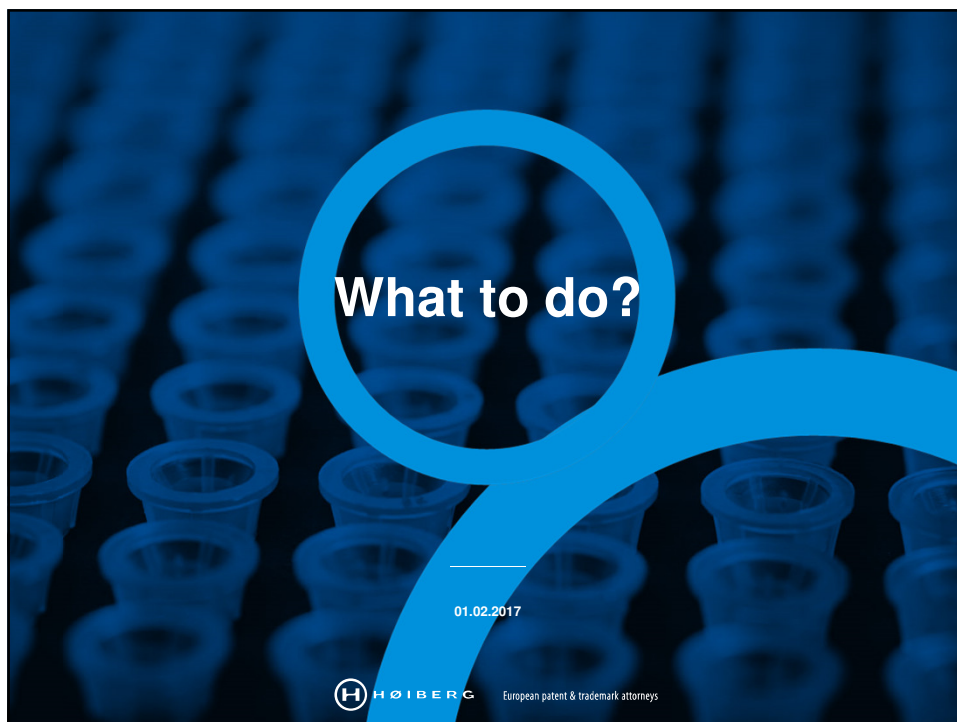
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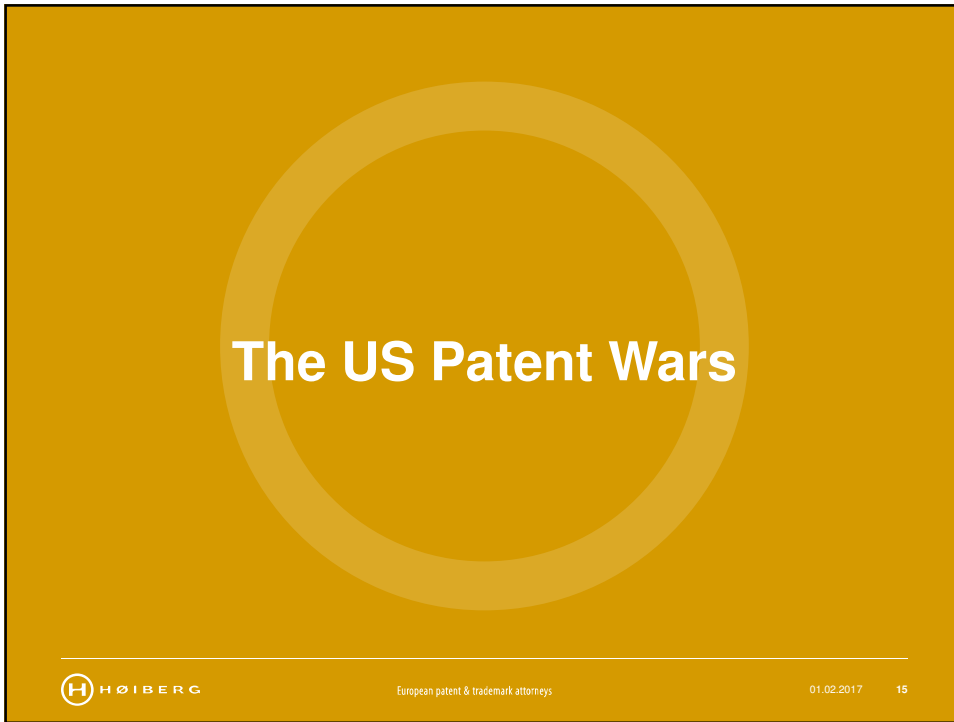
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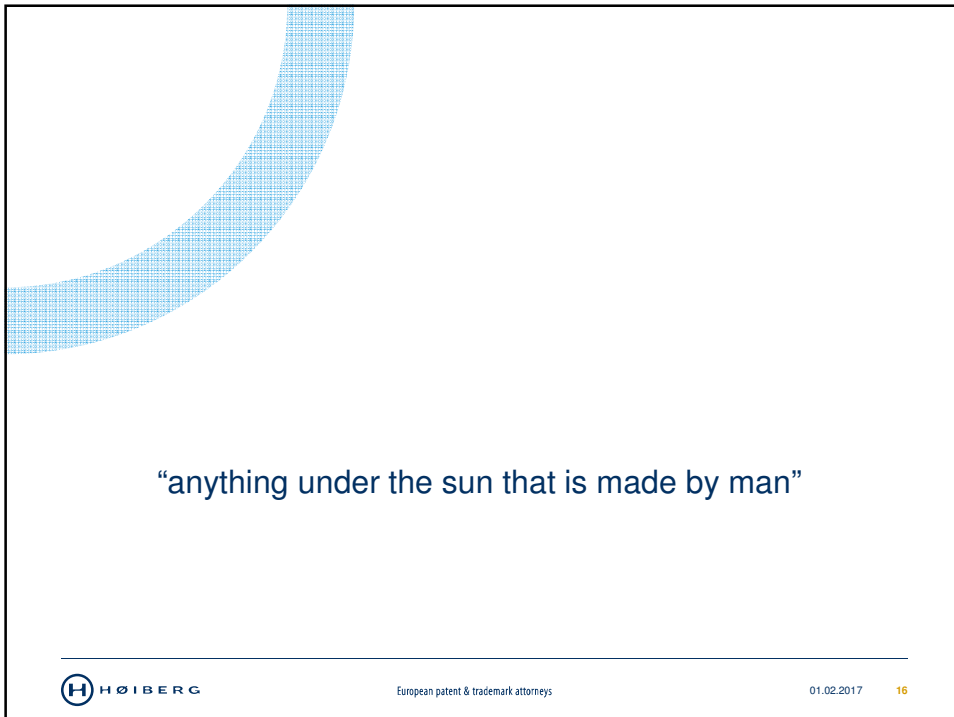
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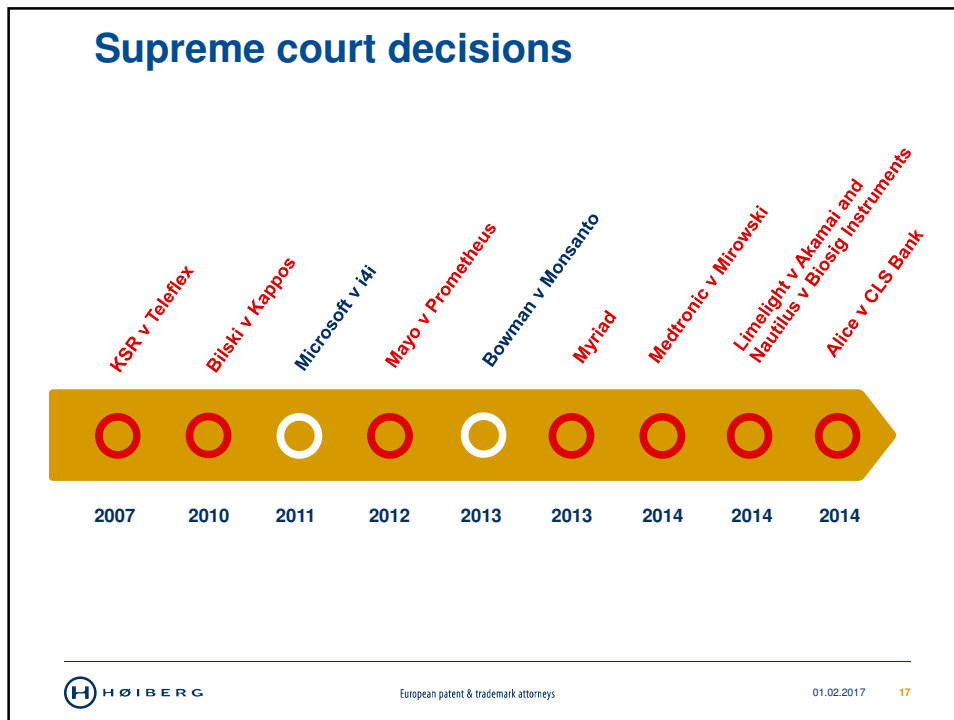
The US Patent Wars

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“anything under the sun that is made by man”

 HØIBERG European patent & trademark attorneys 01.02.2017 16



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H Ø I B E R G European patent & trademark attorneys 01.02.2017 18

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 HØIBERG European patent & trademark attorneys 01.02.2017 21

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- Myriad Genetics proprietor to a number of US patents
- Patent claims:
 - "isolated" human deoxyribonucleic acid (DNA) sequences "BRCA1" and "BRCA2"; and
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 HØIBERG European patent & trademark attorneys 01.02.2017 22

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Amazonic acid background

Amazonian cherry tree grows wild in Amazonas

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Applicant has isolated amazonic acid

Has demonstrated effect in treatment of breast and colon cancer

Has created deoxy amazonic acid, with same activity as amazonic.

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Pomelo Juice

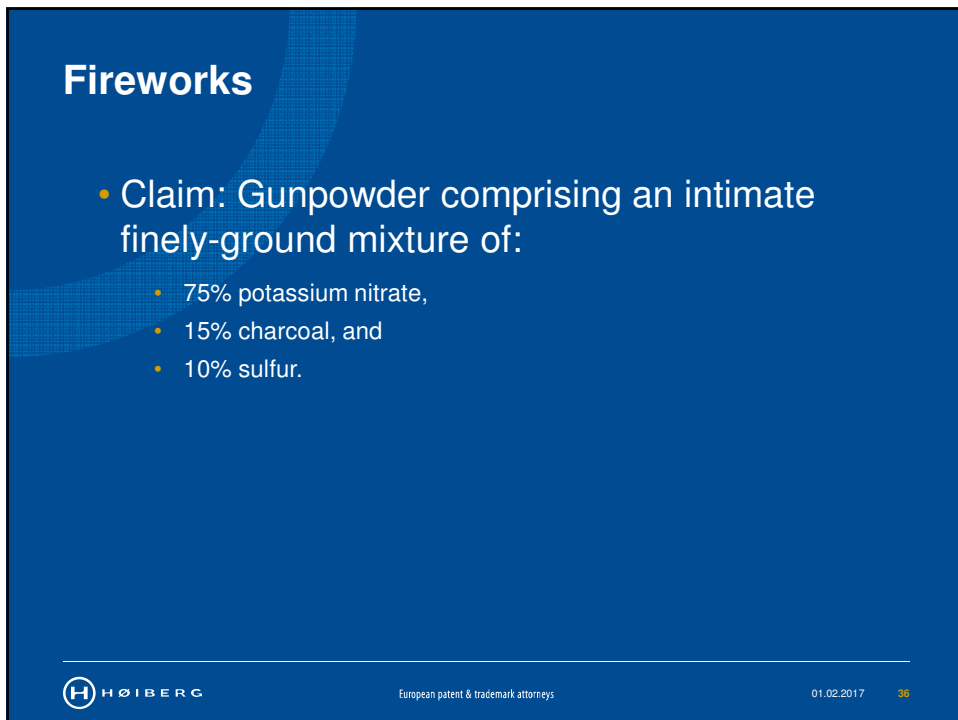
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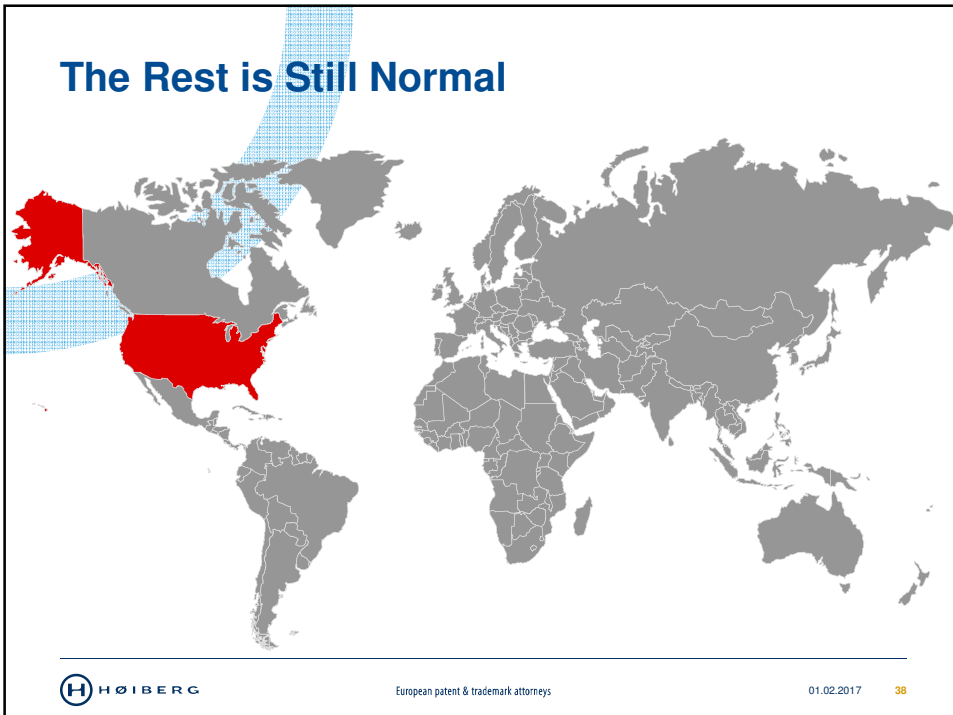
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The components do not occur together in nature.

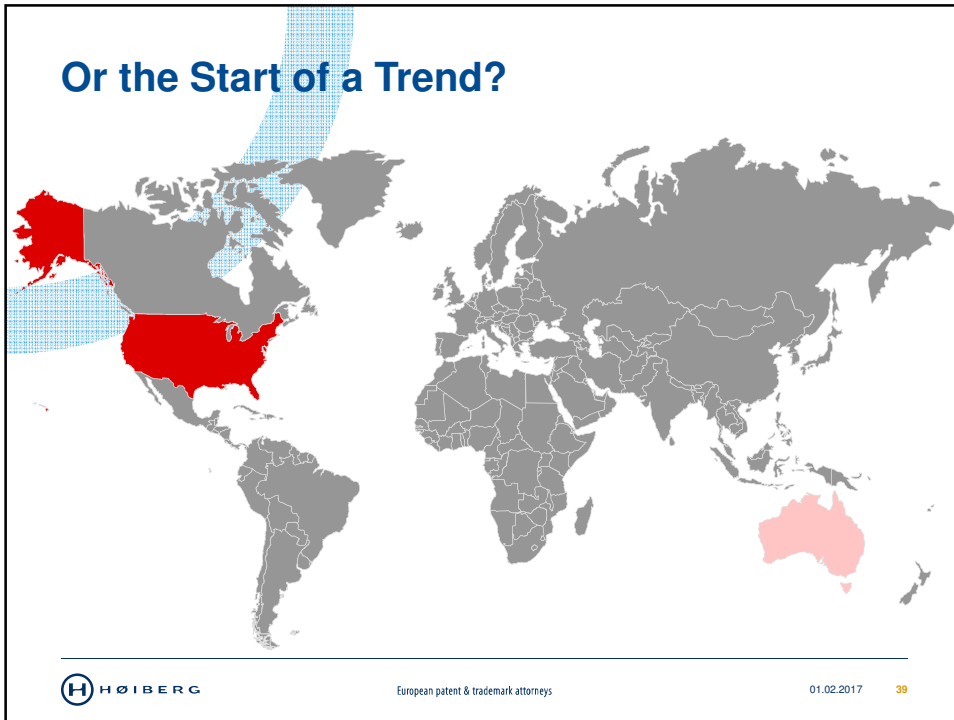
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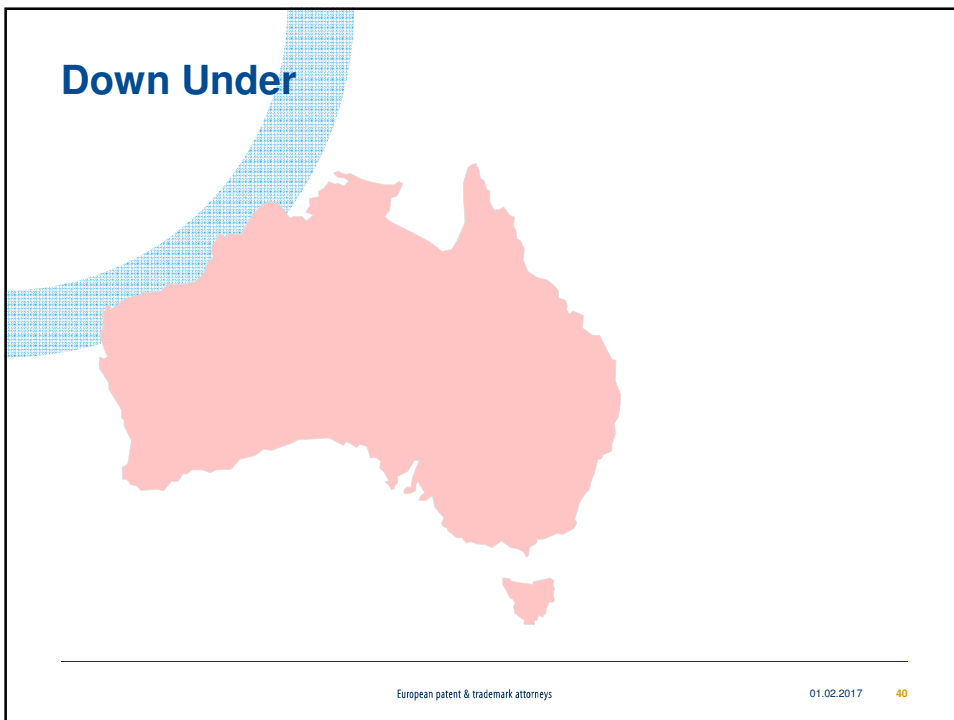
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European patent & trademark attorneys

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- Claims to isolated DNA: not patentable
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- Proteins and peptides are patentable
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- Diagnostic methods are patentable
- Methods of treatment are patentable



Diagnostics


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Diagnostics

Focus on new and patentable analytical methods

Measure the marker using MS, HPLC or similar "high tech"

Recite all steps of analytical method (e.g. PCR, Elisa)

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Diagnosis

Tie the diagnostic method to treatment, follow-on diagnostics

e.g. add a method of treatment step at the end (if tested positive for condition X, treat with drug Y)

Argue that the additional steps are not routine and conventional. If the claim is non-obvious, it should be patentable.

Compound patents

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Add synthesis claims – recombinant or synthetic

Add mutant/derivative/conjugate claims

Do not look for mutants/derivatives in nature

Add method of treatment claims

Other Exceptions in General

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India

- No patents on plants, seeds, or animals
- No patents on drug formulations
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- No patents on new use of known compound
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Exceptions to Patentability

What cannot be done

Jens Viktor Nørgaard
01.02.2017

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Speaker / CV



Jens Viktor Nørgaard

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Agenda

Stem cells
Plant varieties
Products of nature
Laws of nature
Abstract ideas

Why Exceptions



- Ethics, morale
- Non-technical
- Alternative types of protection
- Courts' interpretation of the law
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East meets West

USA

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Stem cells (European Exemption)

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European patent & trademark attorneys
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Plant Varieties - Background

New plant varieties can be Protected (UPOV; CPVO)

European exception

Breeder's & farmer's privilege

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European patent & trademark attorneys
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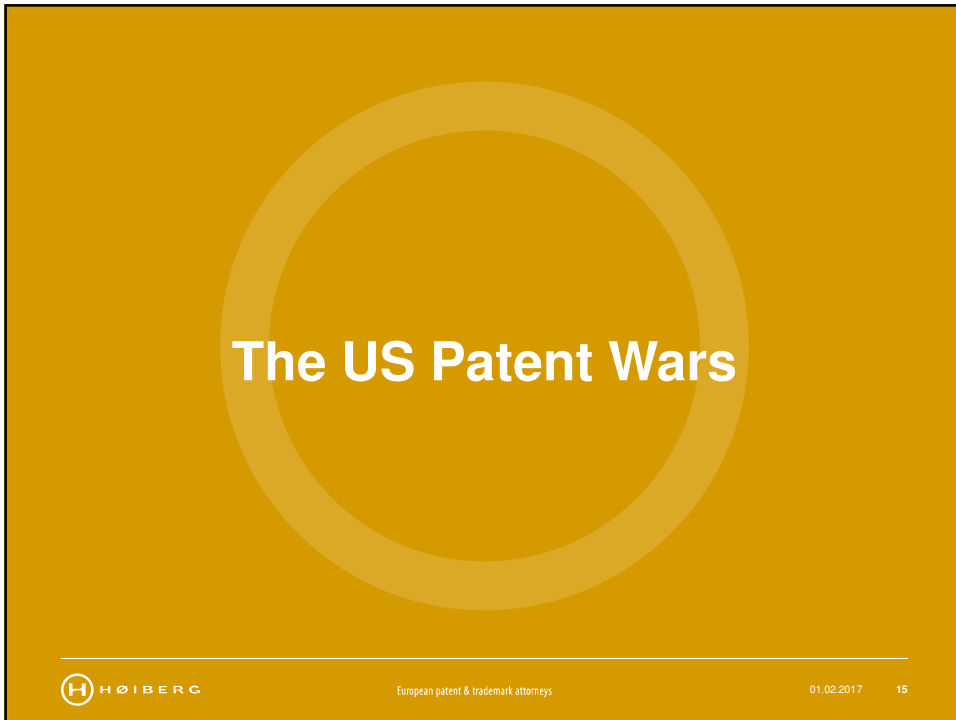
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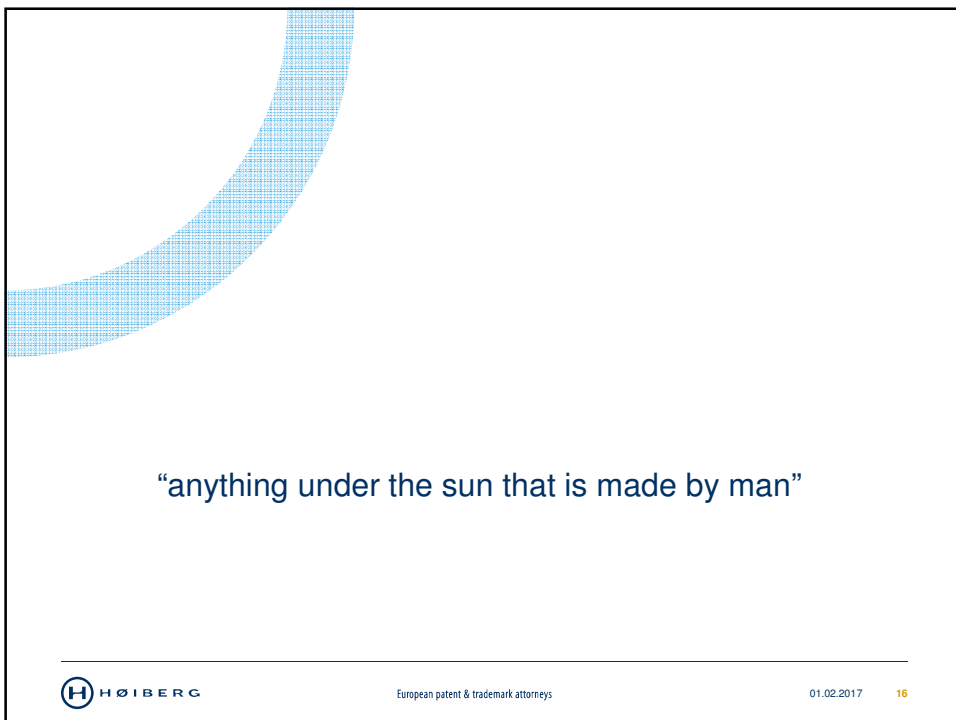
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 HØIBERG European patent & trademark attorneys 01.02.2017 15

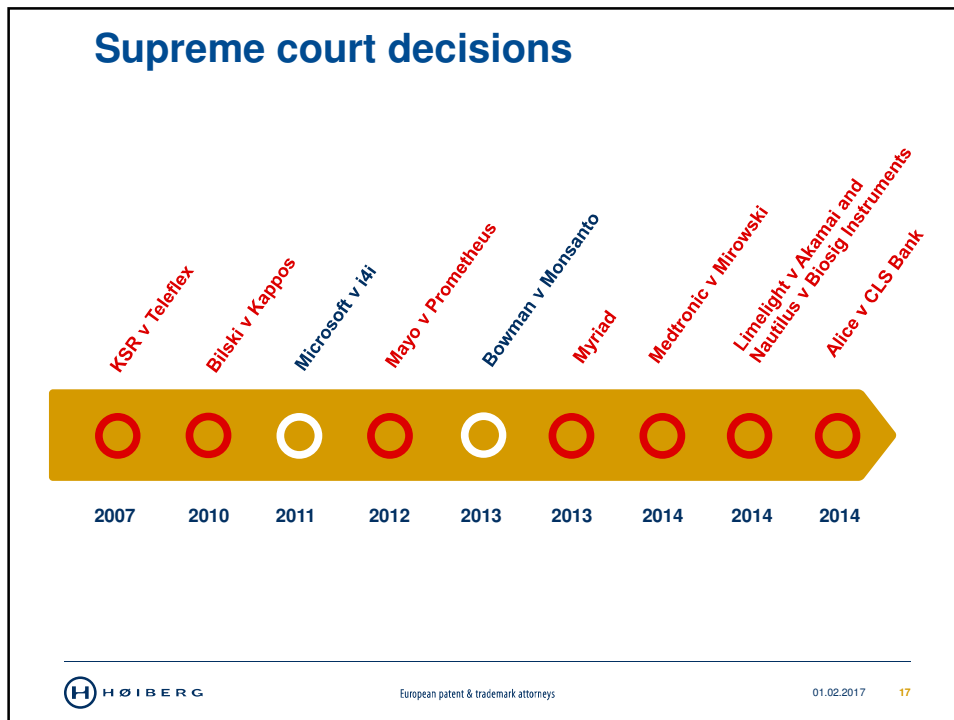
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 HØIBERG European patent & trademark attorneys 01.02.2017 16

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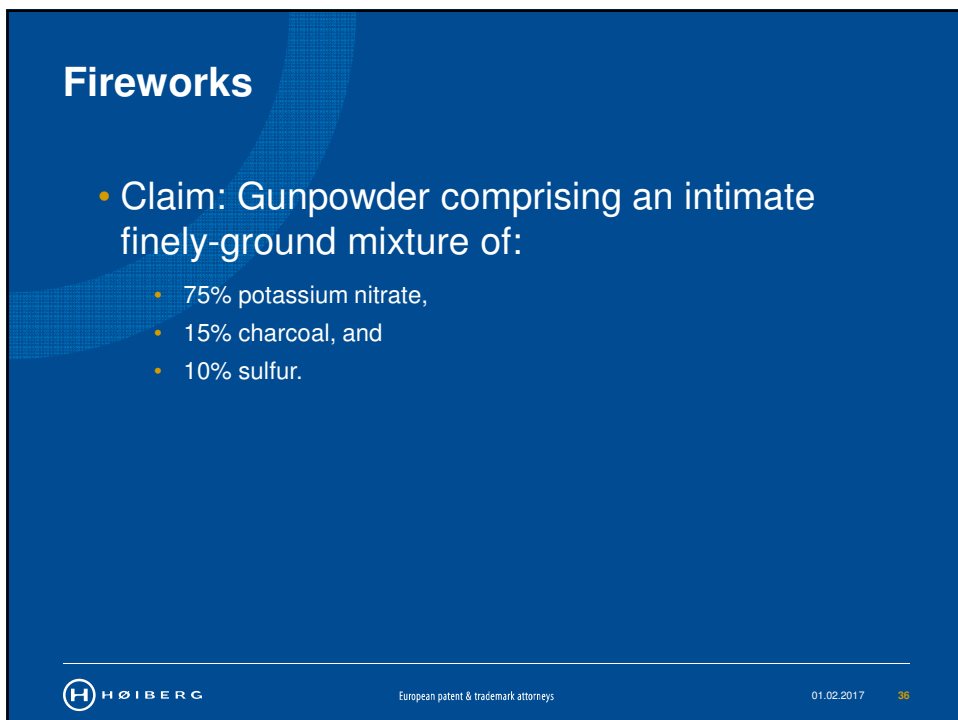
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Gunpowder

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Fireworks

- Claim: Gunpowder comprising an intimate finely-ground mixture of:
 - 75% potassium nitrate,
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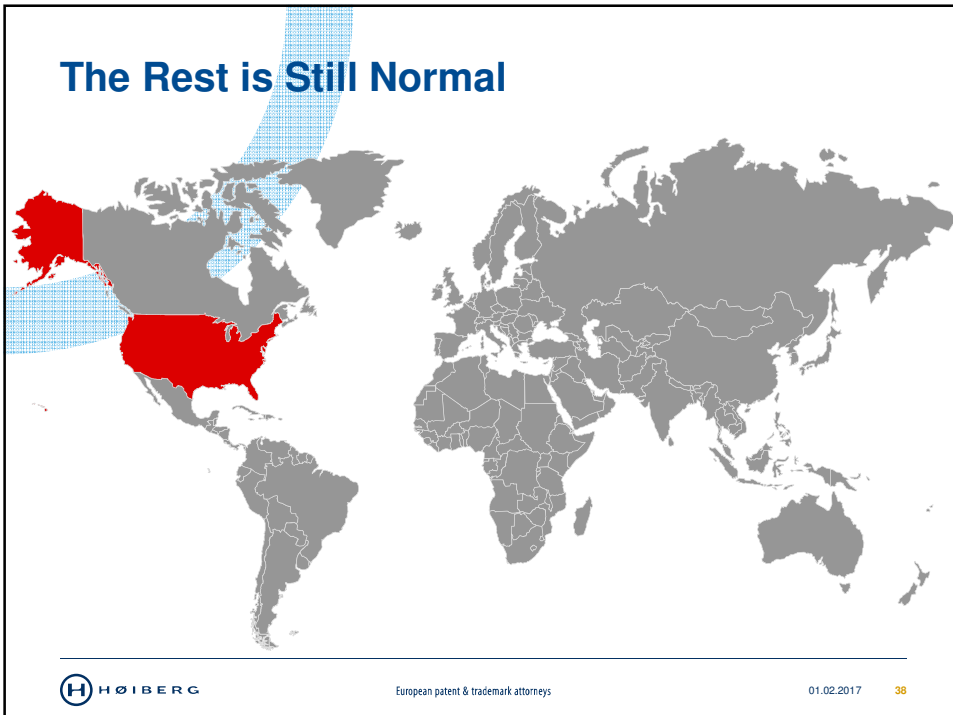
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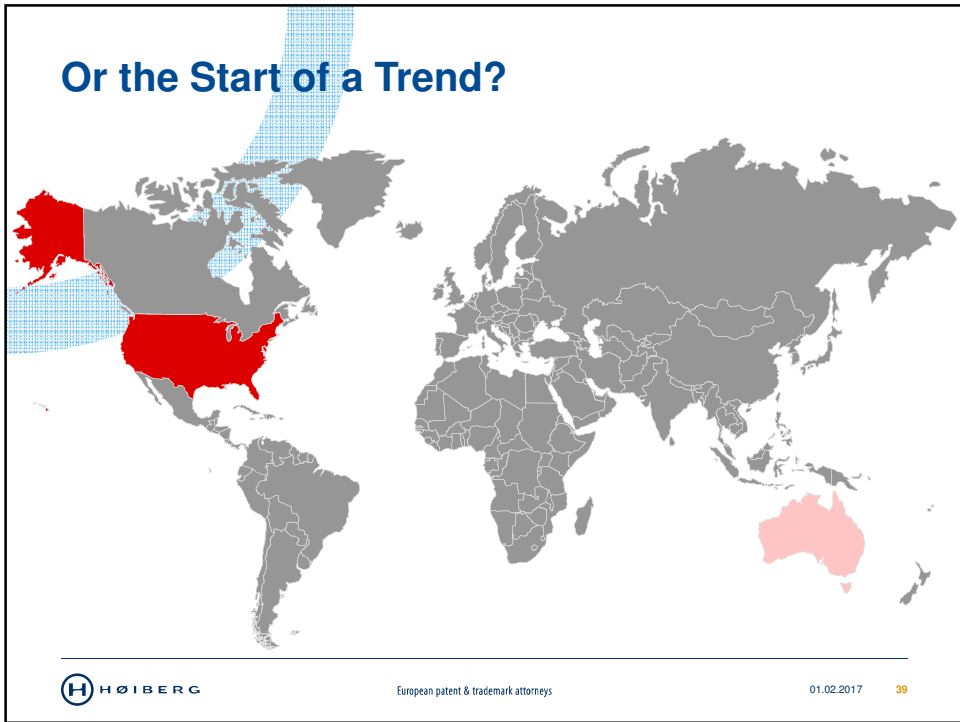
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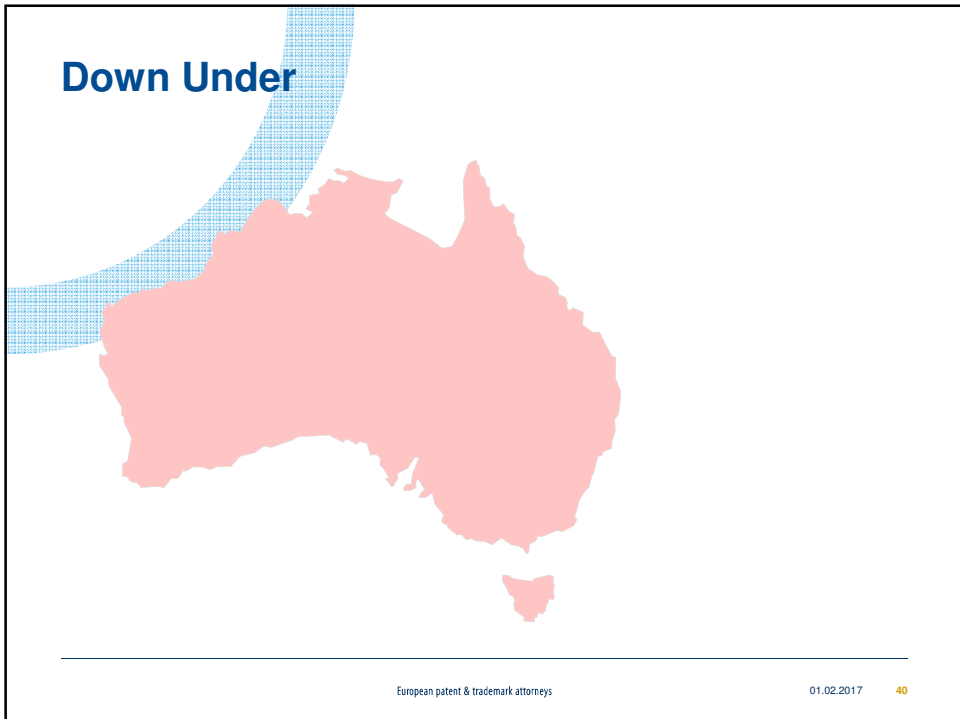
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European patent & trademark attorneys
01.02.2017 39

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European patent & trademark attorneys
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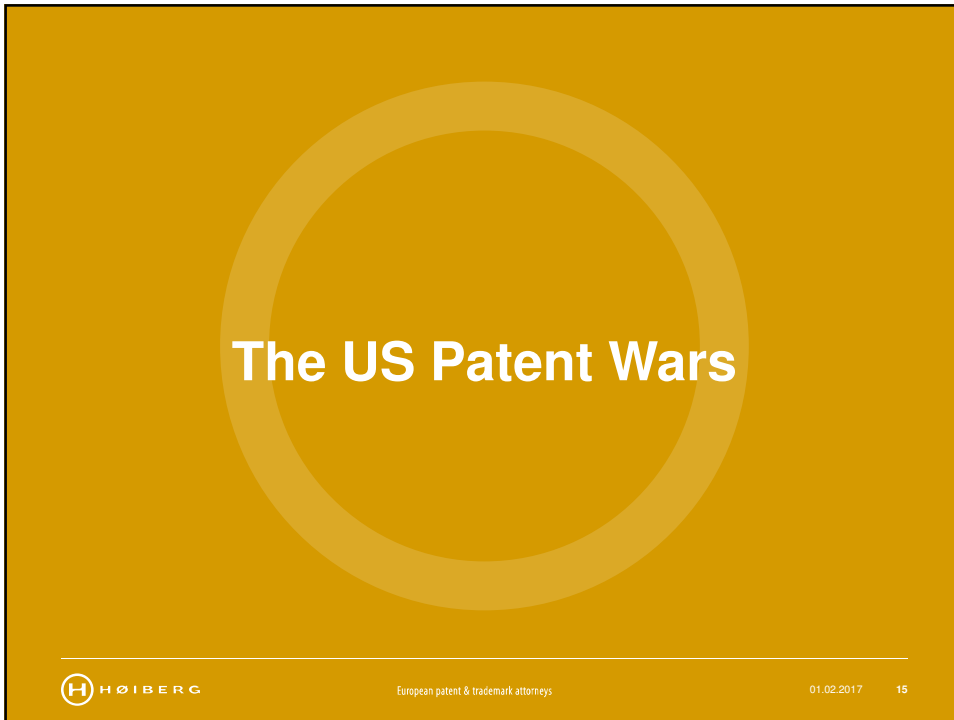
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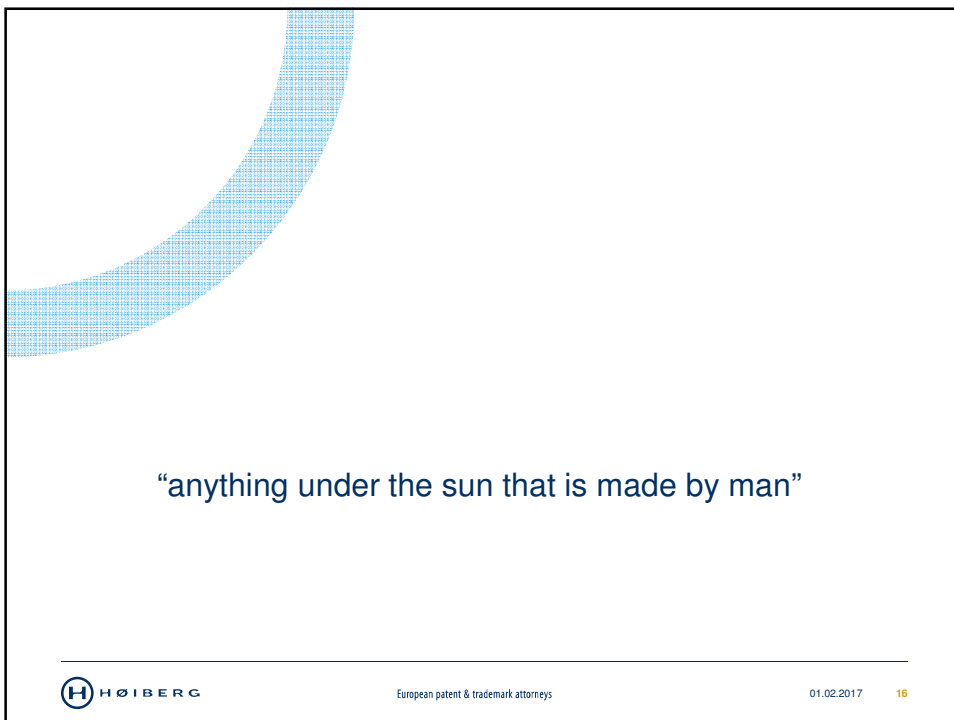
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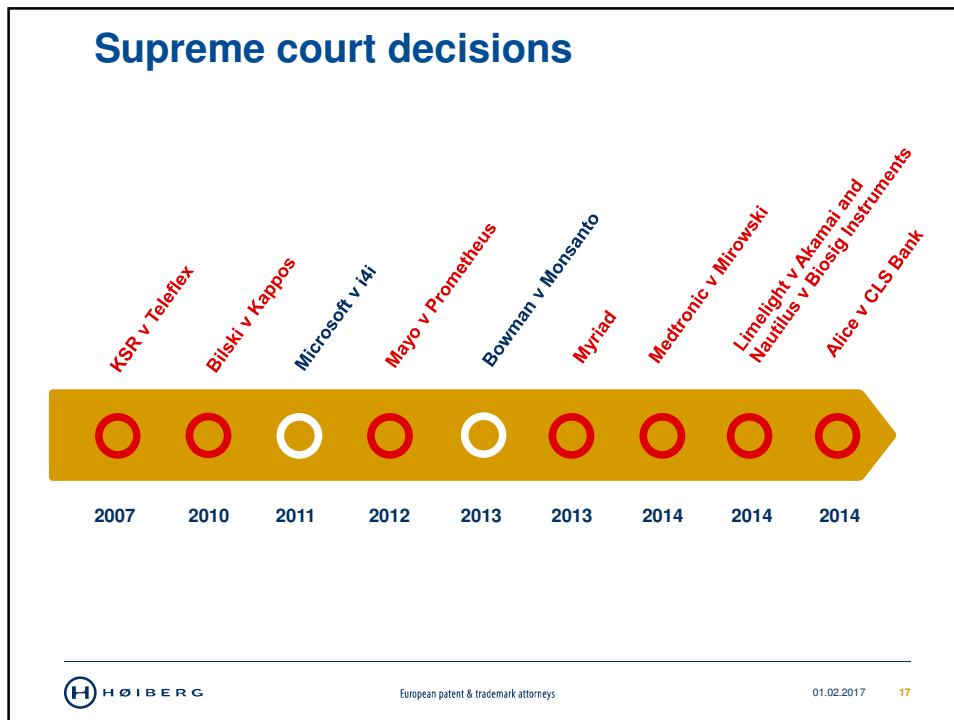
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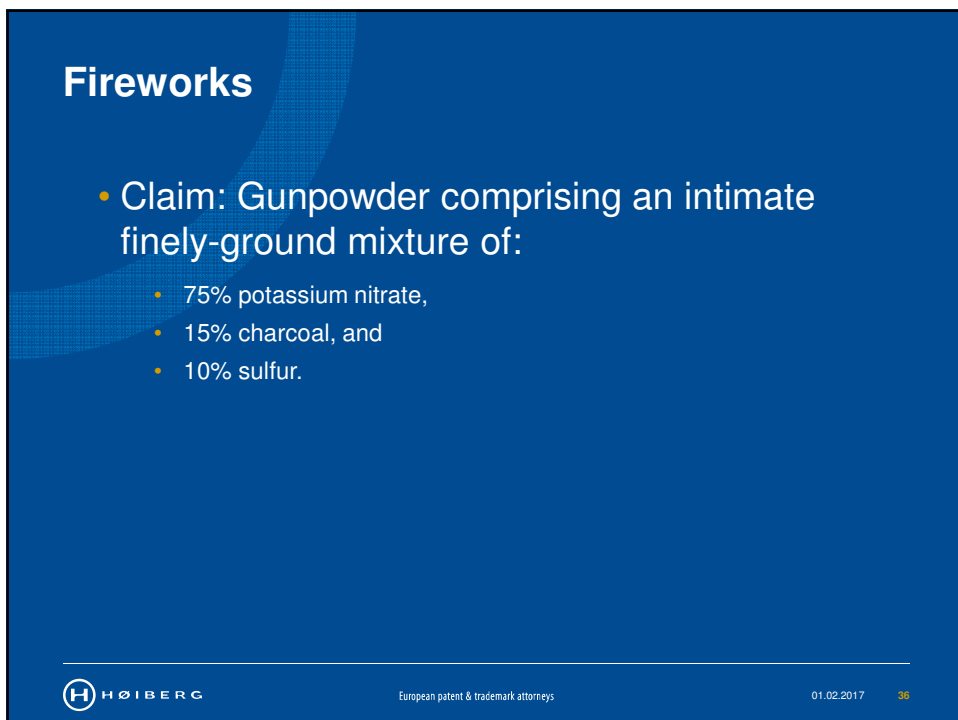
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- Claim: Gunpowder comprising an intimate finely-ground mixture of:
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 HØIBERG European patent & trademark attorneys 01.02.2017 96

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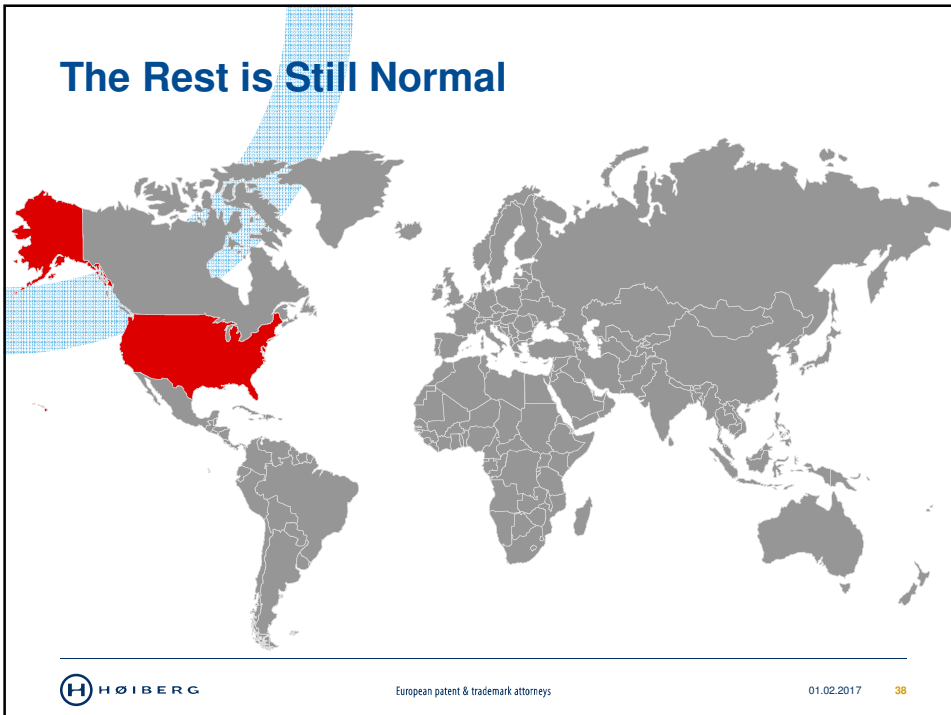
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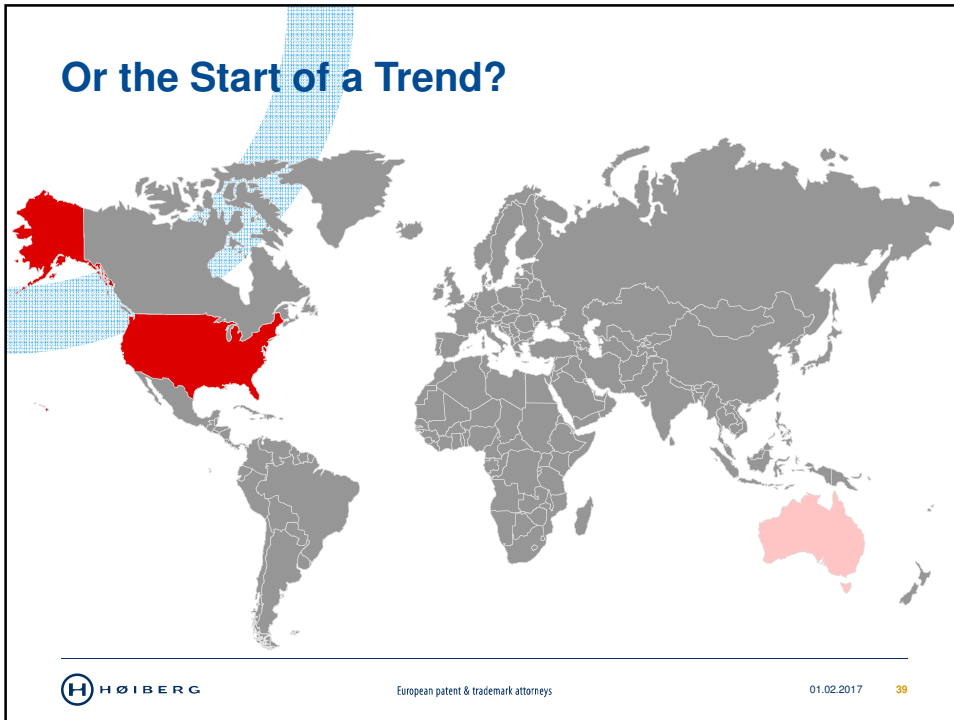
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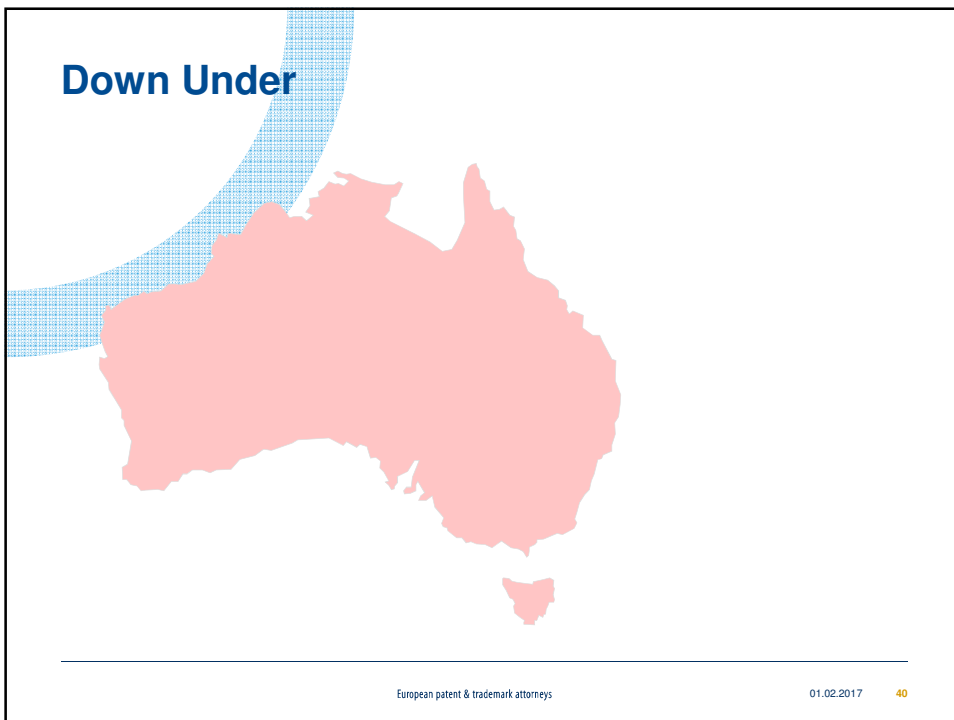
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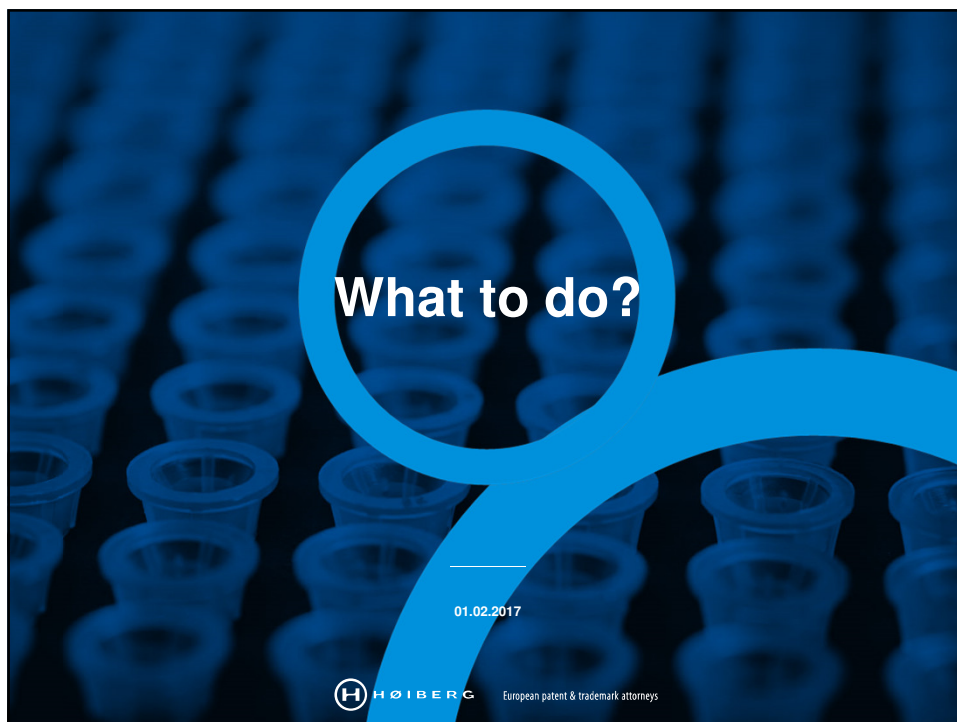
01.02.2017 40

Recent Decision from AU High Court


- Myriad Genetic's Australian patent on BRCA1 and BRCA2 mutations.
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Guidance from AU Patent Office

- Proteins and peptides are patentable
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- Diagnostic methods are patentable
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Diagnostics


 HØIBERG European patent & trademark attorneys 01.02.2017 45

Diagnostics

Focus on new and patentable analytical methods

Measure the marker using MS, HPLC or similar "high tech"

Recite all steps of analytical method (e.g. PCR, Elisa)

 HØIBERG European patent & trademark attorneys 01.02.2017 46

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Tie the diagnostic method to treatment, follow-on diagnostics

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Compound patents

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Other Exceptions in General

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- No patents on plants, seeds, or animals
- No patents on drug formulations
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Thank you
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Exceptions to Patentability

What cannot be done

Jens Viktor Nørgaard
01.02.2017

 HØIBERG European patent & trademark attorneys

Speaker / CV



Jens Viktor Nørgaard

Head of Biotechnology & Plant sciences
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jvn@hoiberg.com

 HØIBERG European patent & trademark attorneys 01.02.2017

Agenda

Stem cells
Plant varieties
Products of nature
Laws of nature
Abstract ideas

Why Exceptions



- Ethics, morale
- Non-technical
- Alternative types of protection
- Courts' interpretation of the law
- Public/lobbyist pressure

East meets West

USA

Common law country

Governed by

- the law
- Court interpretation

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Legislator decides

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European patent & trademark attorneys
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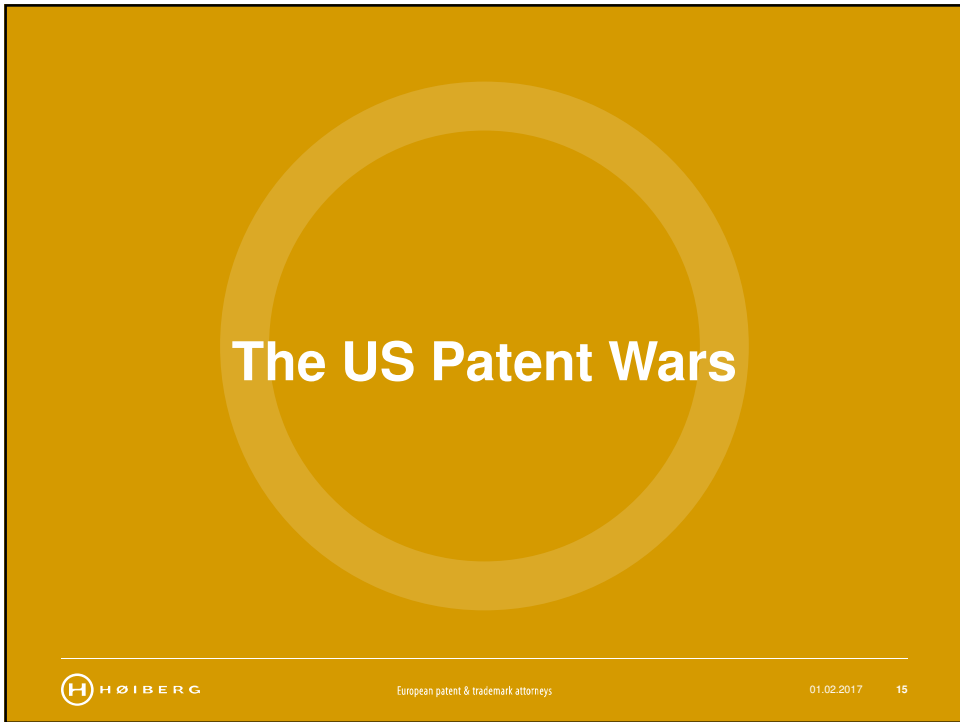
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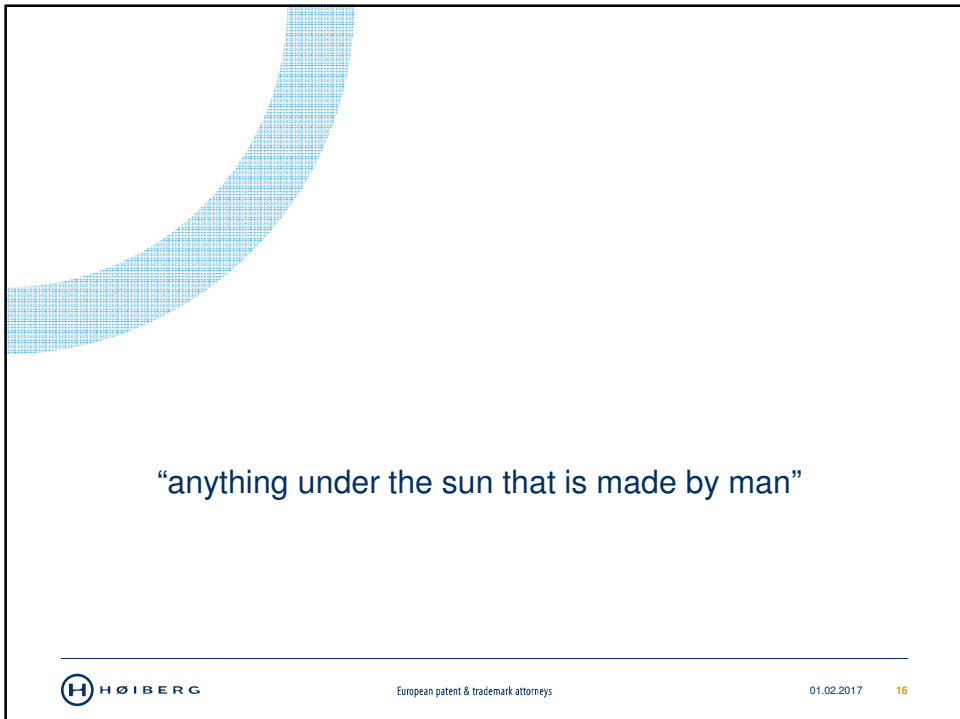
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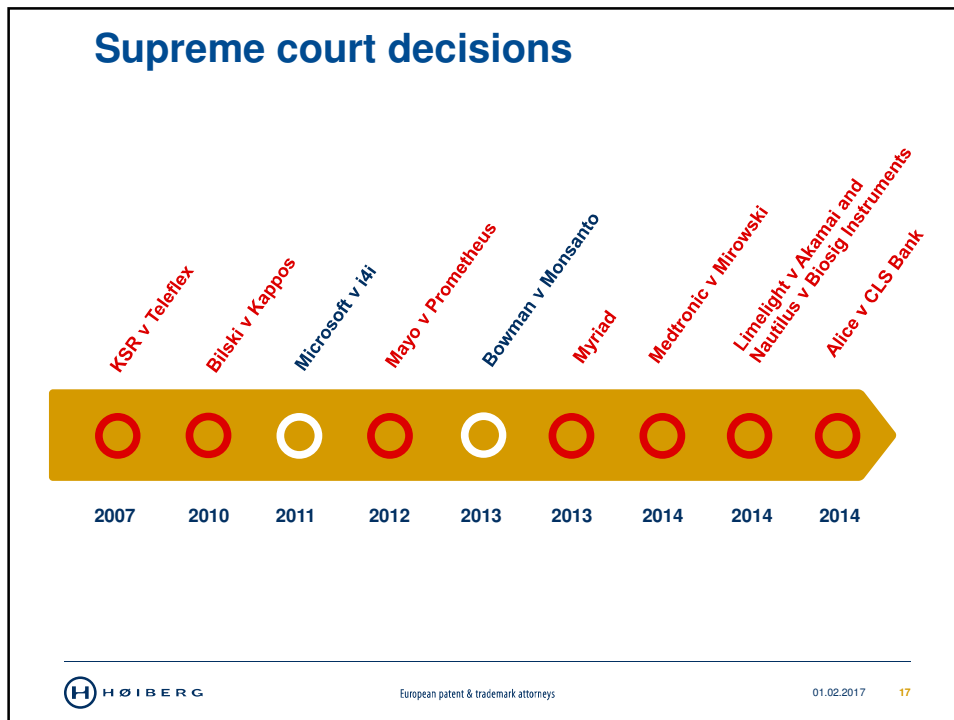
The US Patent Wars

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“anything under the sun that is made by man”

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What does the law say

Patent eligible subject matter (§ 101):
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machine,
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- Prometheus Labs had rights to a series of US patents directed to a diagnostic method.
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 HØIBERG European patent & trademark attorneys 01.02.2017 21

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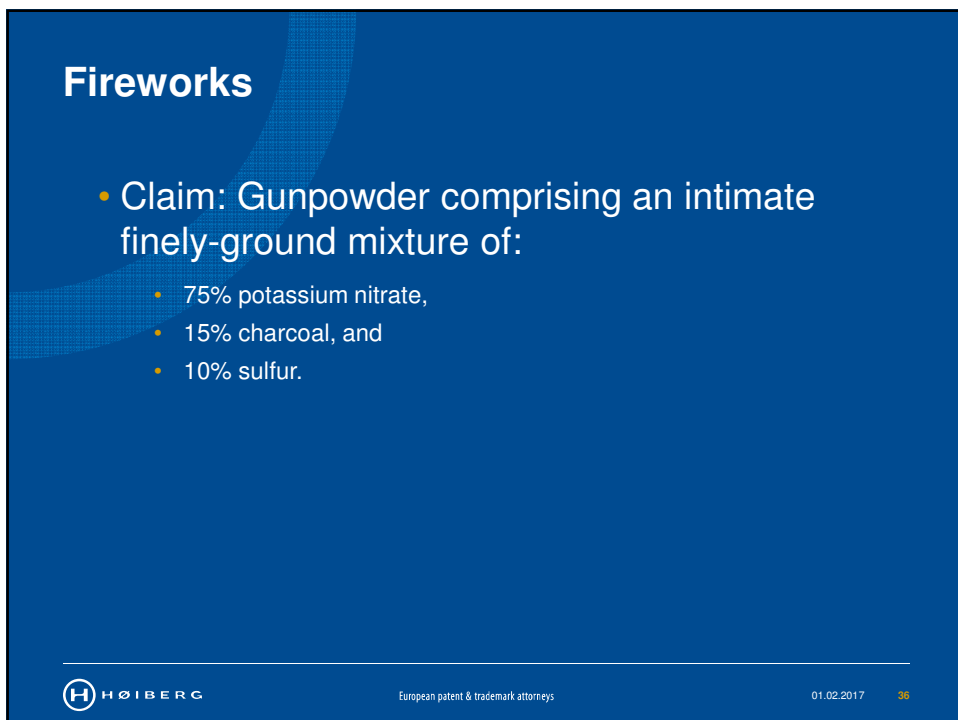


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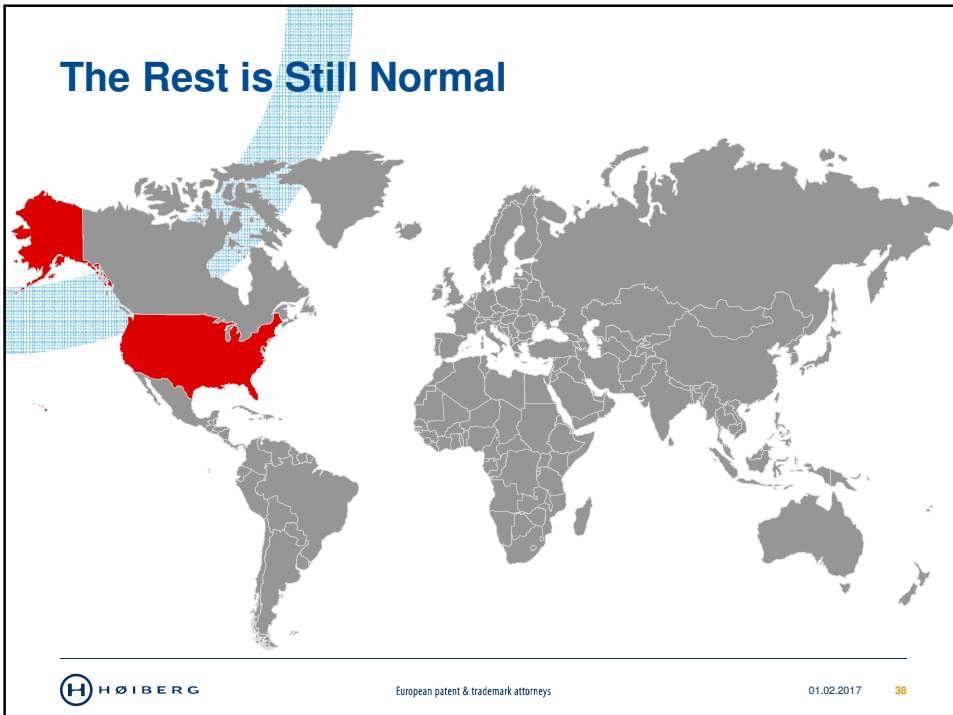
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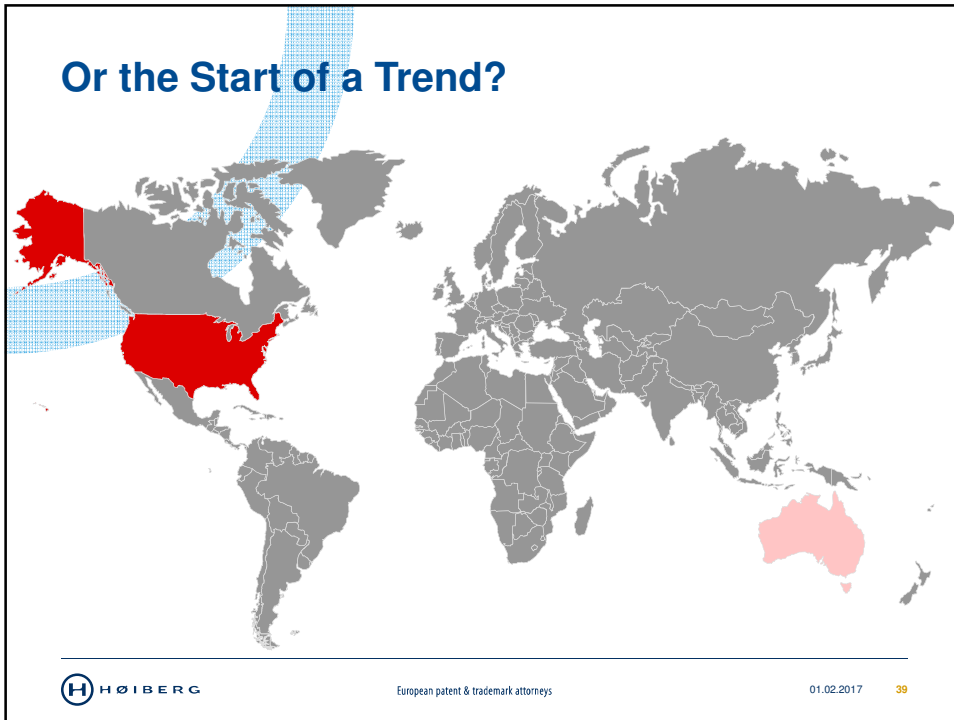
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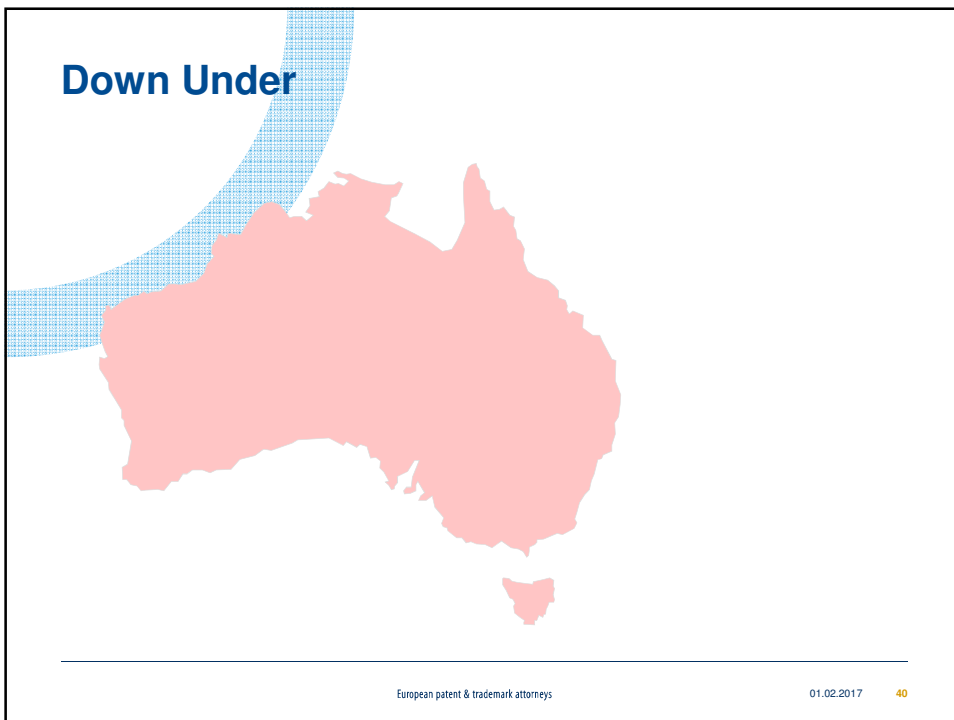
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 HØIBERG European patent & trademark attorneys 01.02.2017 45

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Products of nature
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European patent & trademark attorneys
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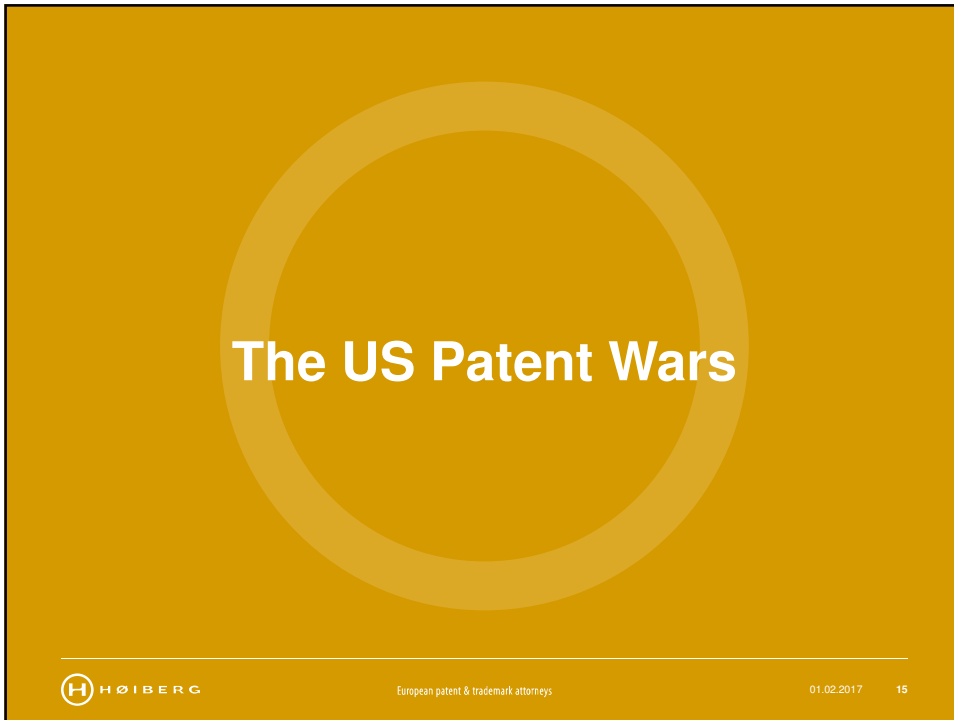
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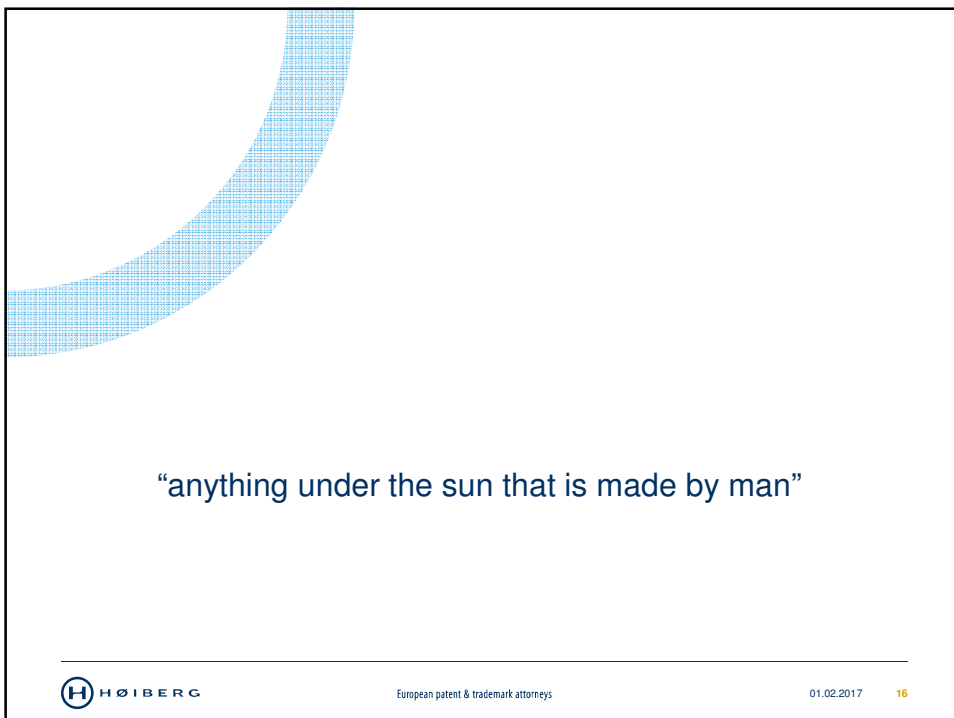
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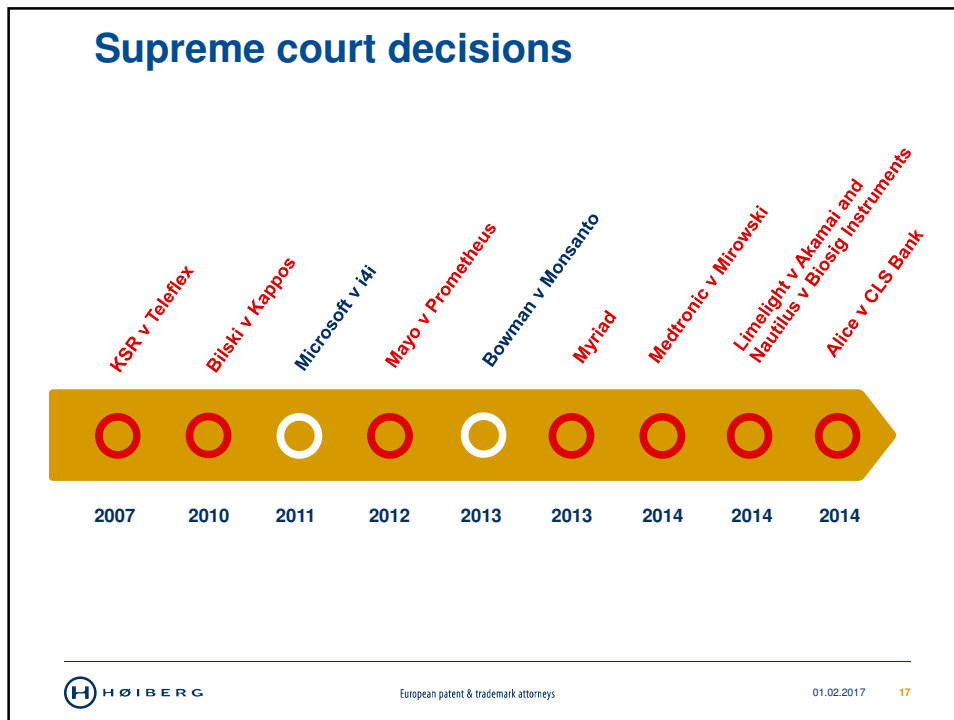
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H Ø I B E R G European patent & trademark attorneys 01.02.2017 18

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 HØIBERG European patent & trademark attorneys 01.02.2017 22

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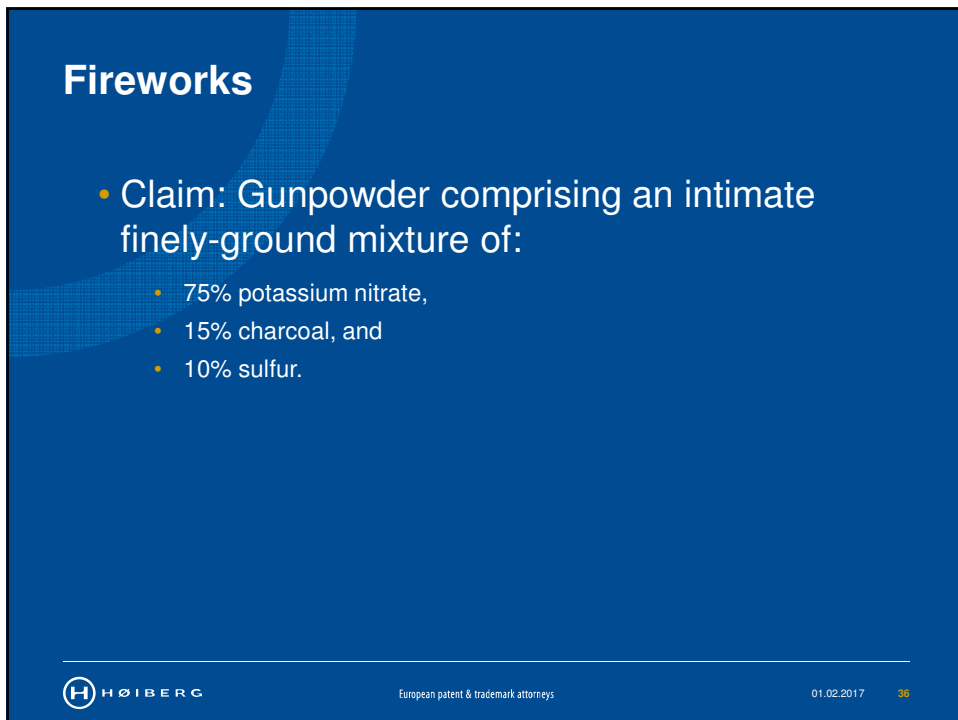
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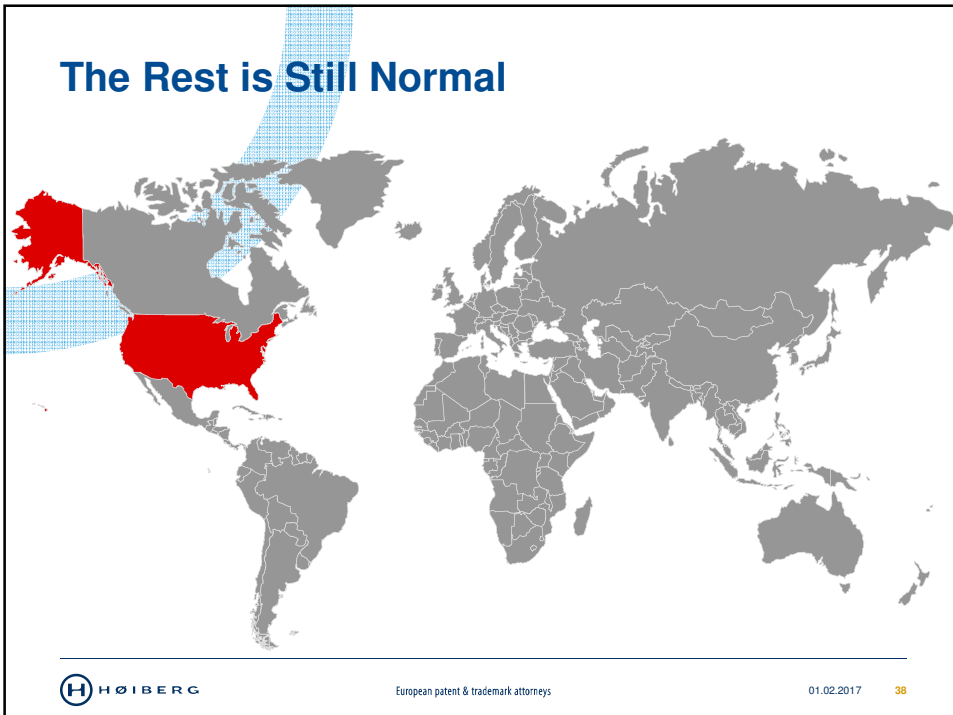
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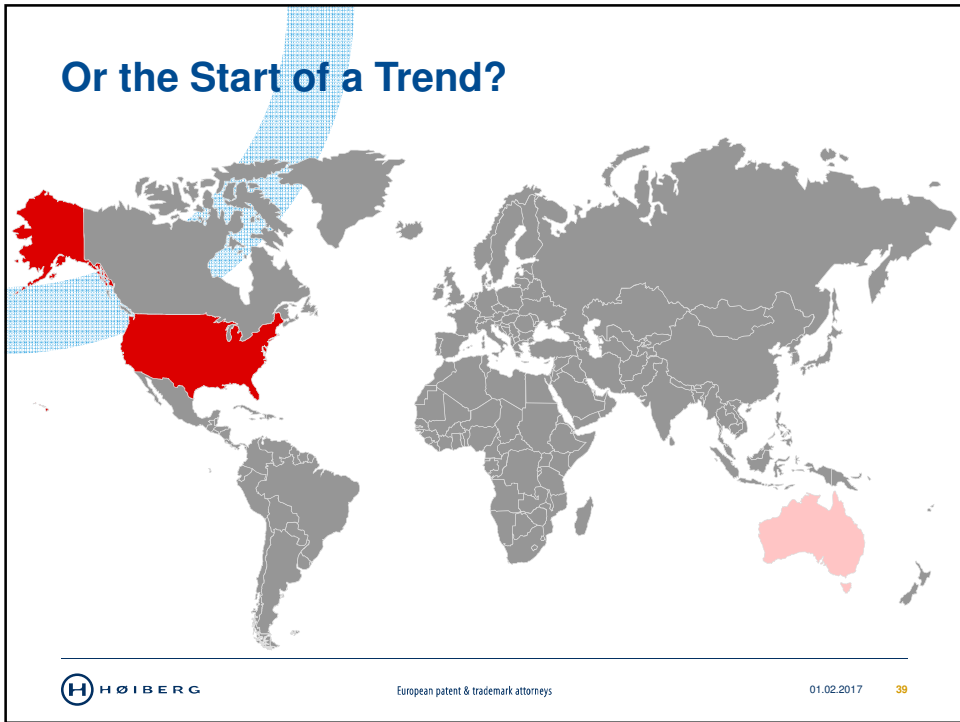
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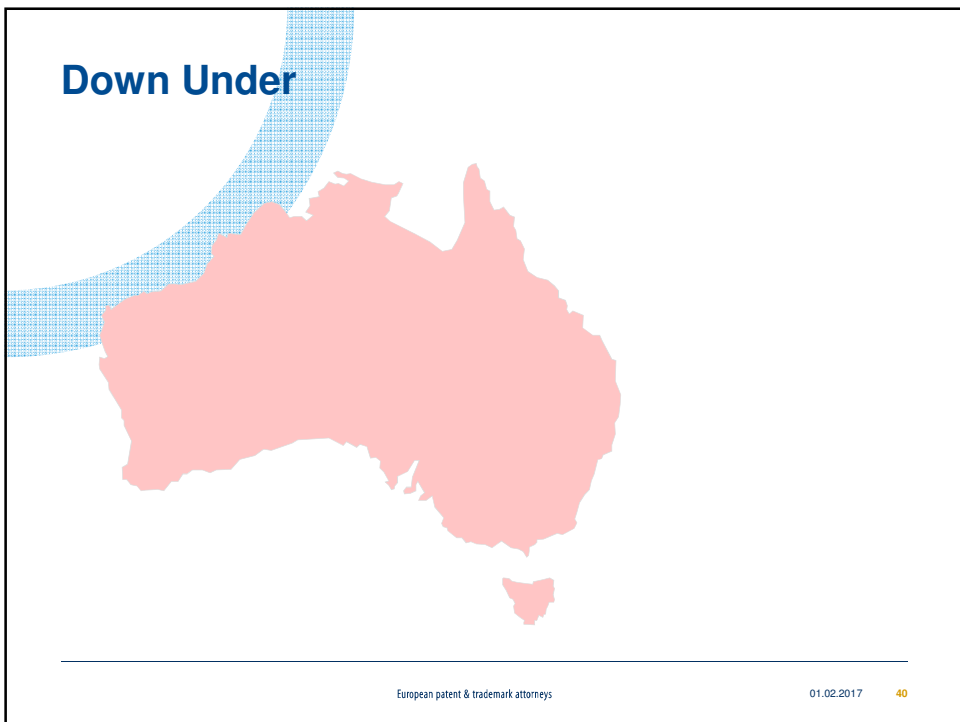
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European patent & trademark attorneys
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European patent & trademark attorneys
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Diagnostics


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Diagnostics

Focus on new and patentable analytical methods

Measure the marker using MS, HPLC or similar "high tech"

Recite all steps of analytical method (e.g. PCR, Elisa)

 HØIBERG European patent & trademark attorneys 01.02.2017 46

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Tie the diagnostic method to treatment, follow-on diagnostics

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- No patents on plants, seeds, or animals
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Exceptions to Patentability

What cannot be done

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01.02.2017

 HØIBERG European patent & trademark attorneys

Speaker / CV



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Agenda

Stem cells
Plant varieties
Products of nature
Laws of nature
Abstract ideas

Why Exceptions



- Ethics, morale
- Non-technical
- Alternative types of protection
- Courts' interpretation of the law
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East meets West

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Common law country

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- The law:
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Plant Varieties

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New plant varieties can be Protected (UPOV; CPVO)

European exception

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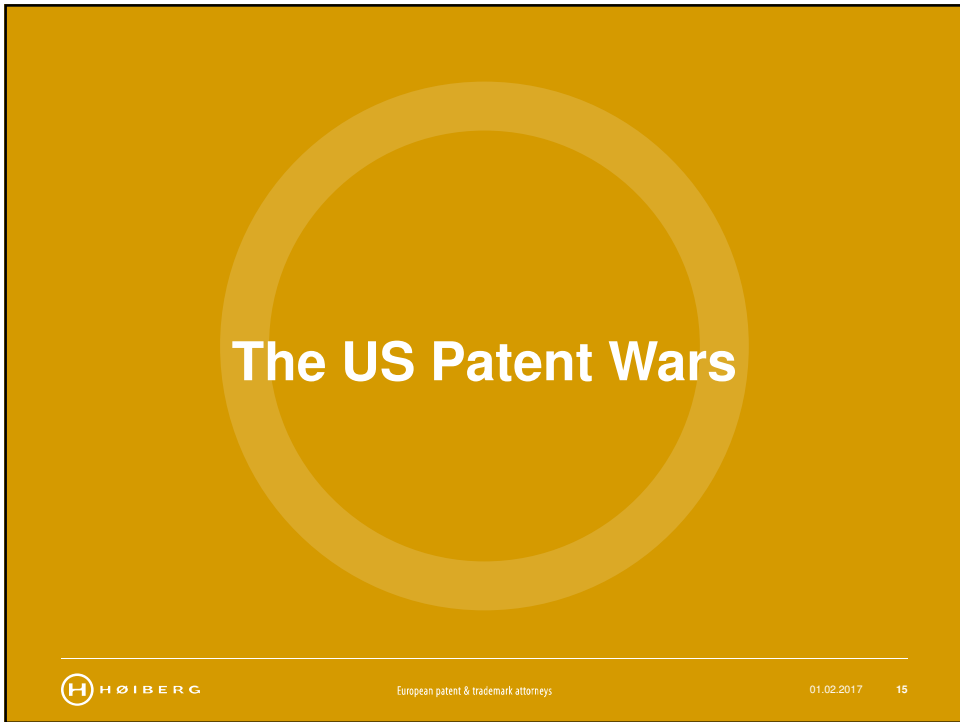
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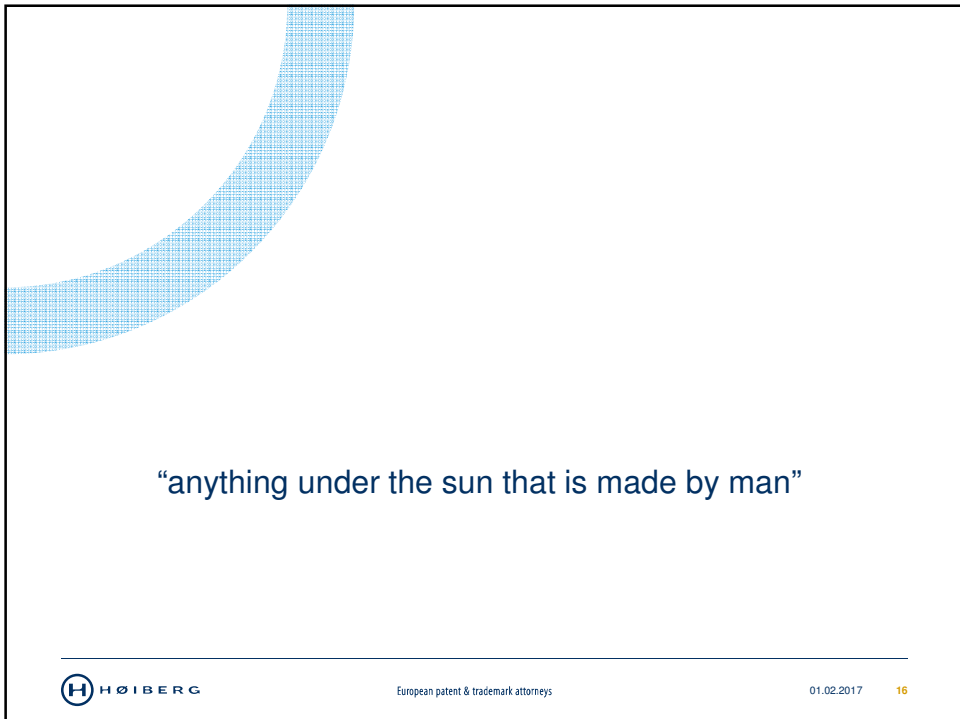
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The US Patent Wars

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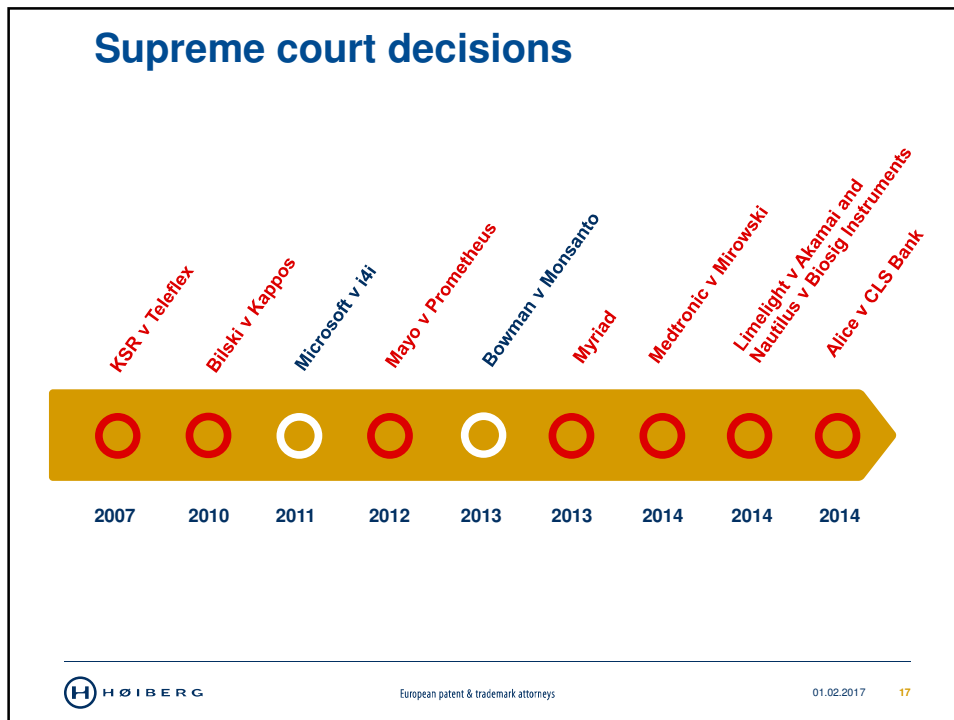
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What does the law say

Patent eligible subject matter (§ 101):
 Whoever invents or discovers any new and useful
process,
machine,
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 any new and useful improvement thereof, may obtain a patent
 therefor, subject to the conditions and requirements of this title.

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Mayo vs. Prometheus

- Prometheus Labs had rights to a series of US patents directed to a diagnostic method.
- The method involved:
 - Determining the level of metabolites of thiopurines
 - Wherein the level indicates a need to increase or decrease the amount of drug to be administered.
- Prometheus sued Mayo Medical Laboratories for infringement of their US patents

Mayo vs. Prometheus


There is a danger that granting patents that tie up use of laws of nature will inhibit future innovation

Provides incentives that lead to creation, invention and discovery

Patent protection is a two-edged sword


Consequences

- No diagnostic patents are granted
- Diagnostic correlation = "law of nature"
- The detection method must be patentable in itself


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Myriad

- Myriad Genetics proprietor to a number of US patents
- Patent claims:
 - "isolated" human deoxyribonucleic acid (DNA) sequences "BRCA1" and "BRCA2"; and
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- It is important to note what is *not* implicated by this decision.
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Claim 18. A method to enable the formulation of customized multi-party risk management contracts having a future time of maturity, the method comprising the steps of:

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- Amazonic acid (anticancer drug from plant)
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Amazonic acid background

Amazonian cherry tree grows wild in Amazonas

It's leaves contain a substance that has anti-cancer effects

Nobody has succeeded in isolating the compound

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Applicant has isolated amazonic acid

Has demonstrated effect in treatment of breast and colon cancer

Has created deoxy amazonic acid, with same activity as amazonic.

Amazonic acid

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Claim 1 is not patentable. Separating the acid from its surrounding material in the leaf has resulted in the purified amazonic acid having not markedly different characteristics from its naturally occurring counterpart.

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1. A composition comprising pomelo juice, and a an effective amount of a preservative.
2. The composition of claim 1 wherein the preservative is 0.5% vitamin E.
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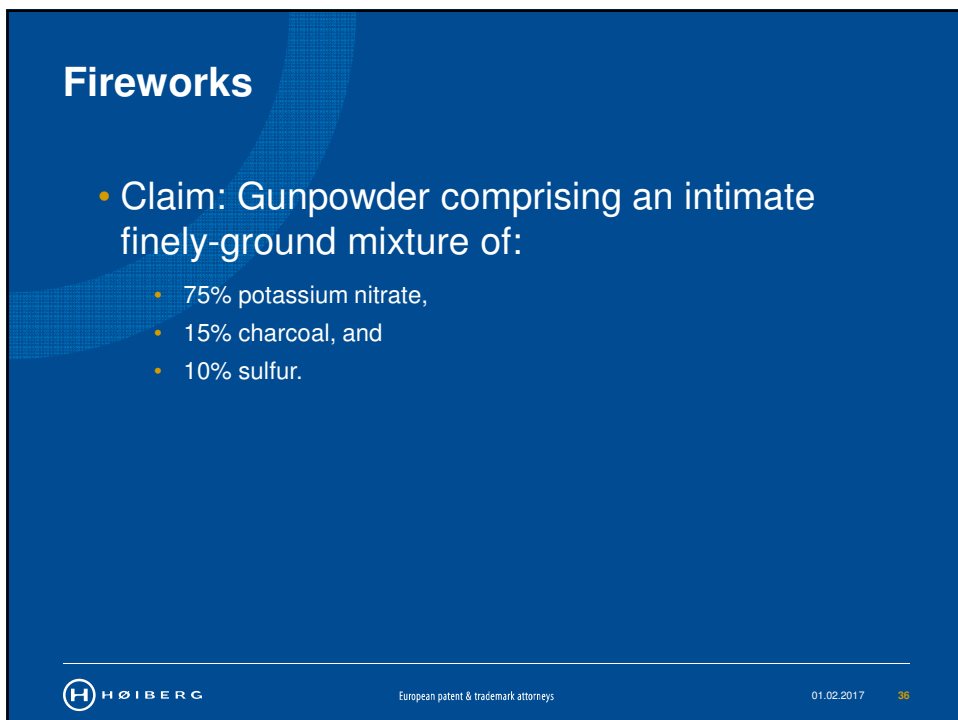
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- Claim: Gunpowder comprising an intimate finely-ground mixture of:
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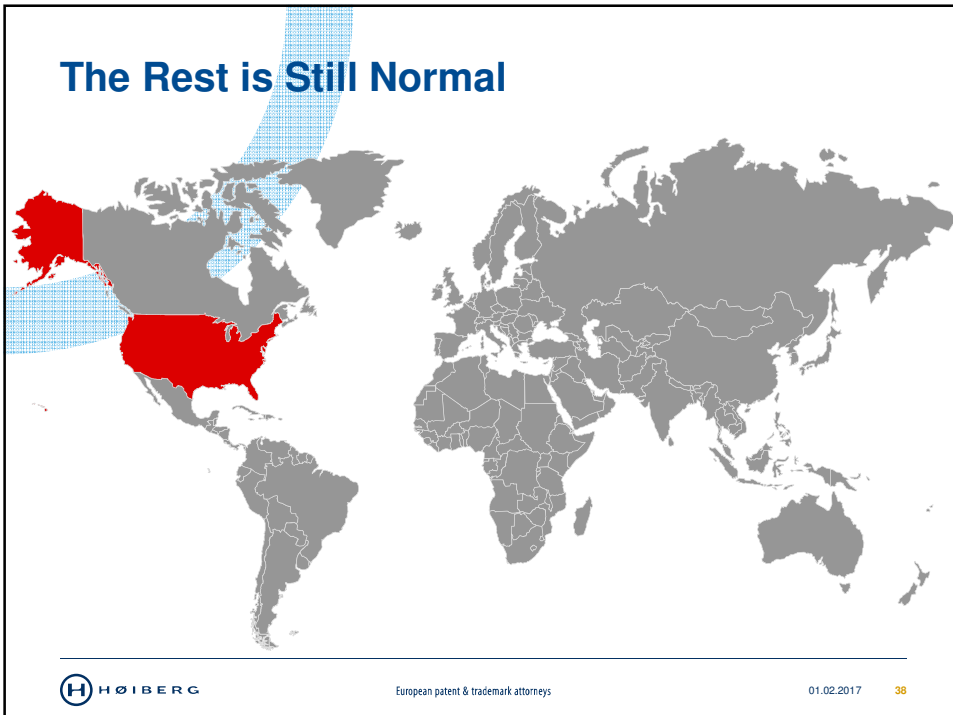
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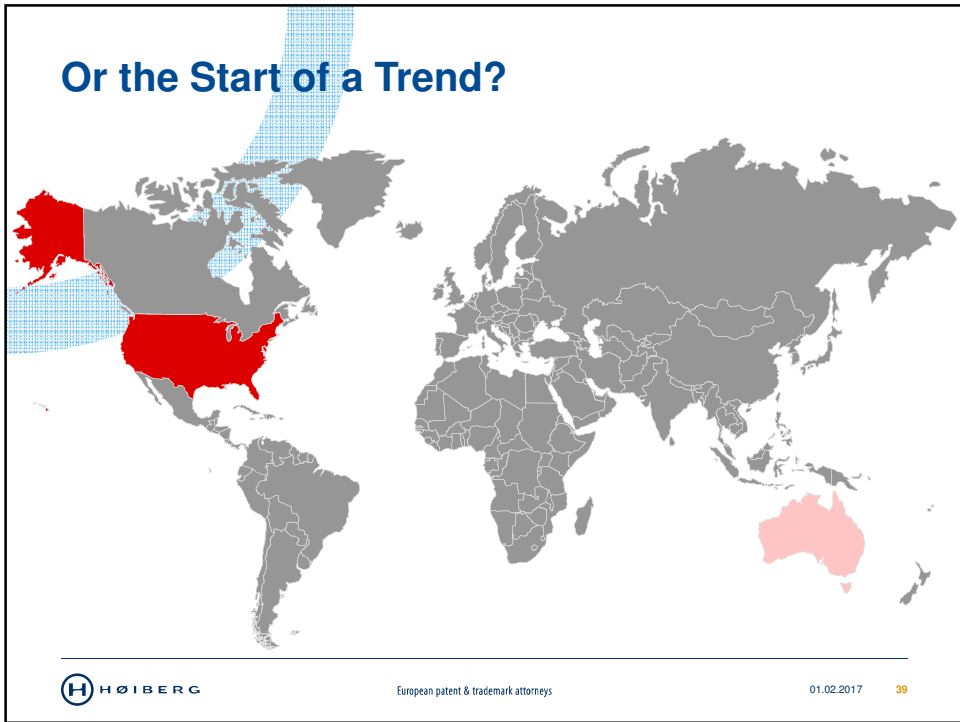
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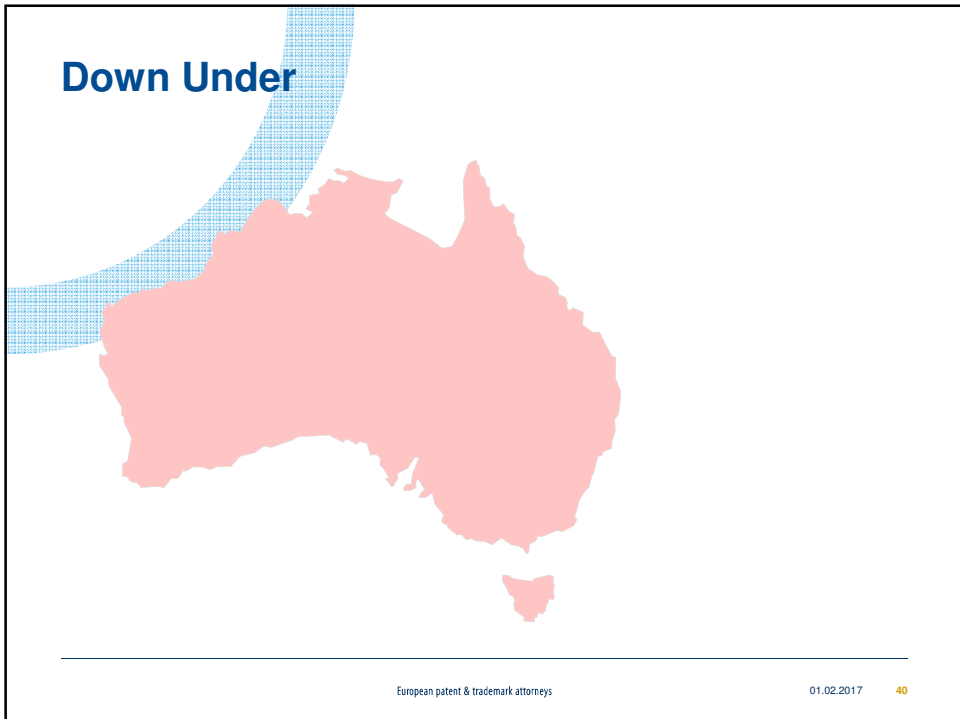
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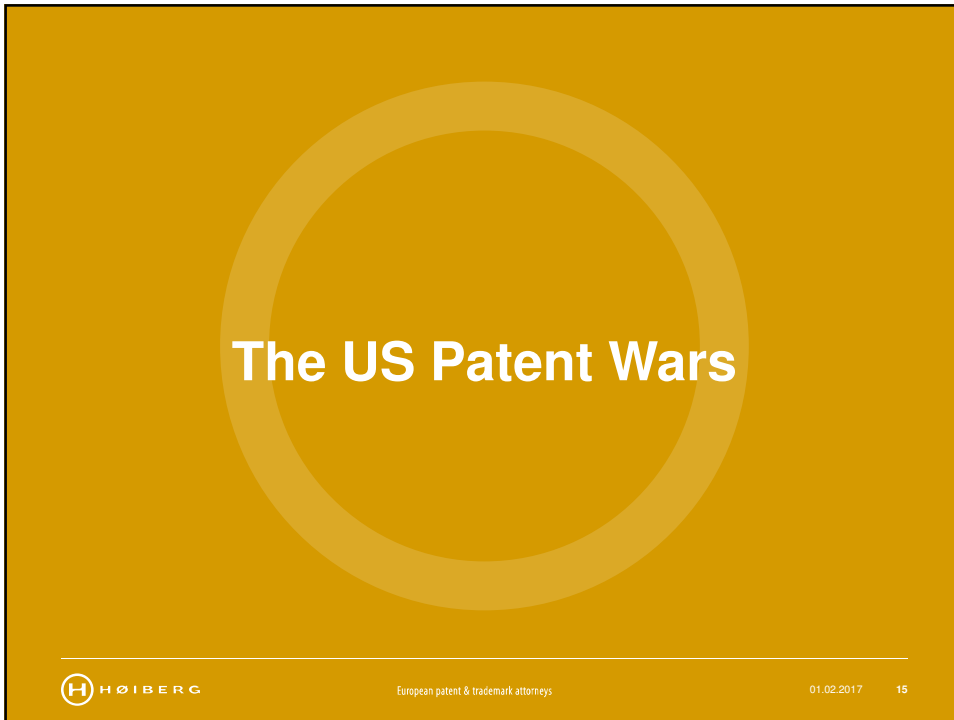
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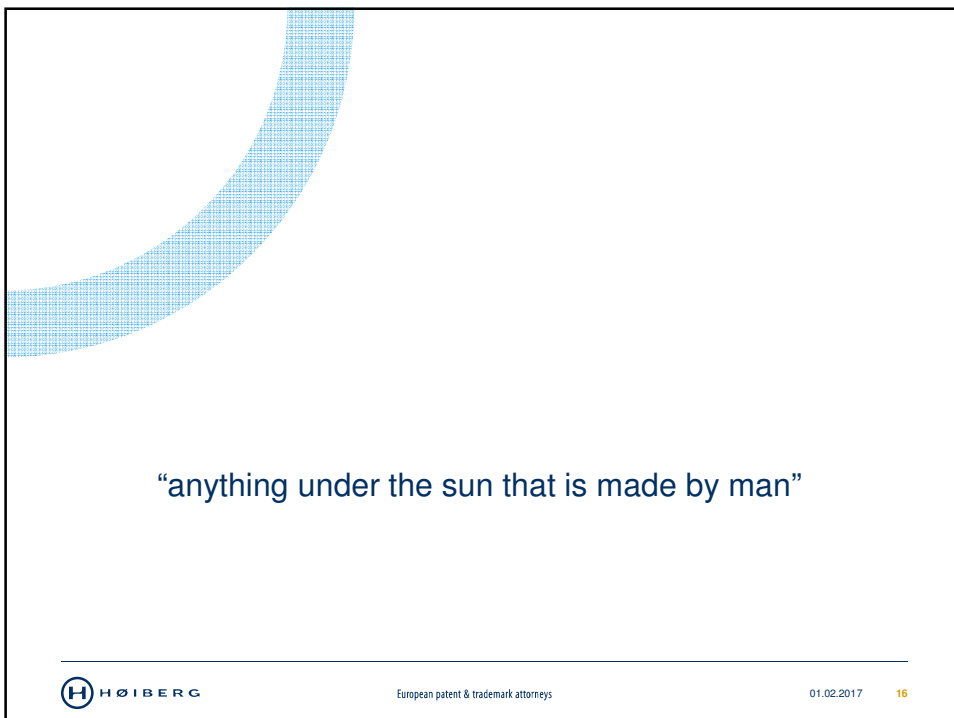
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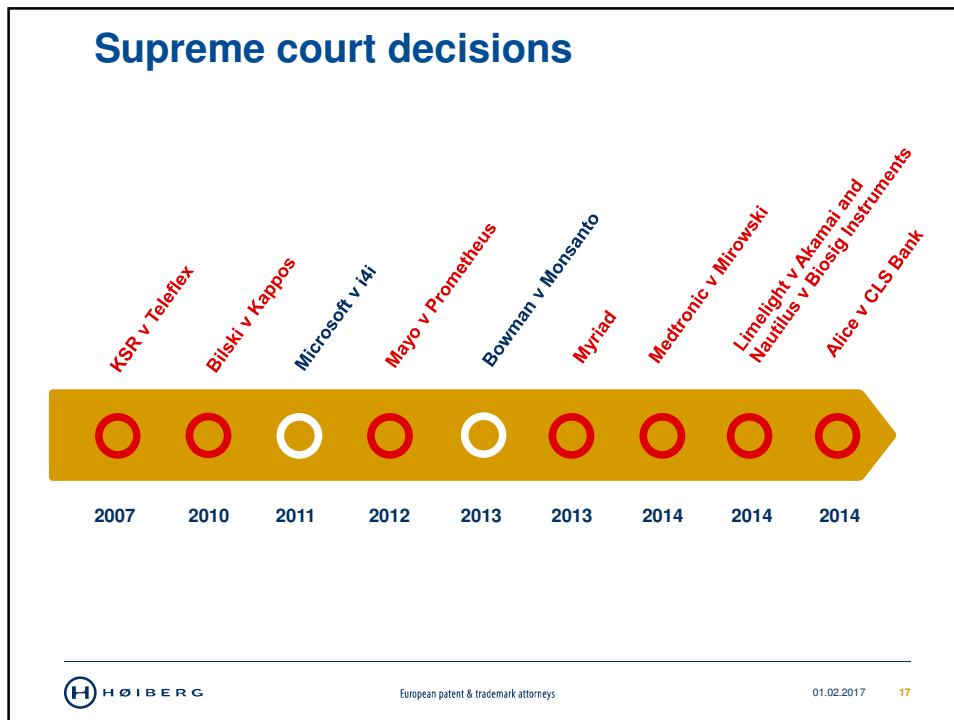
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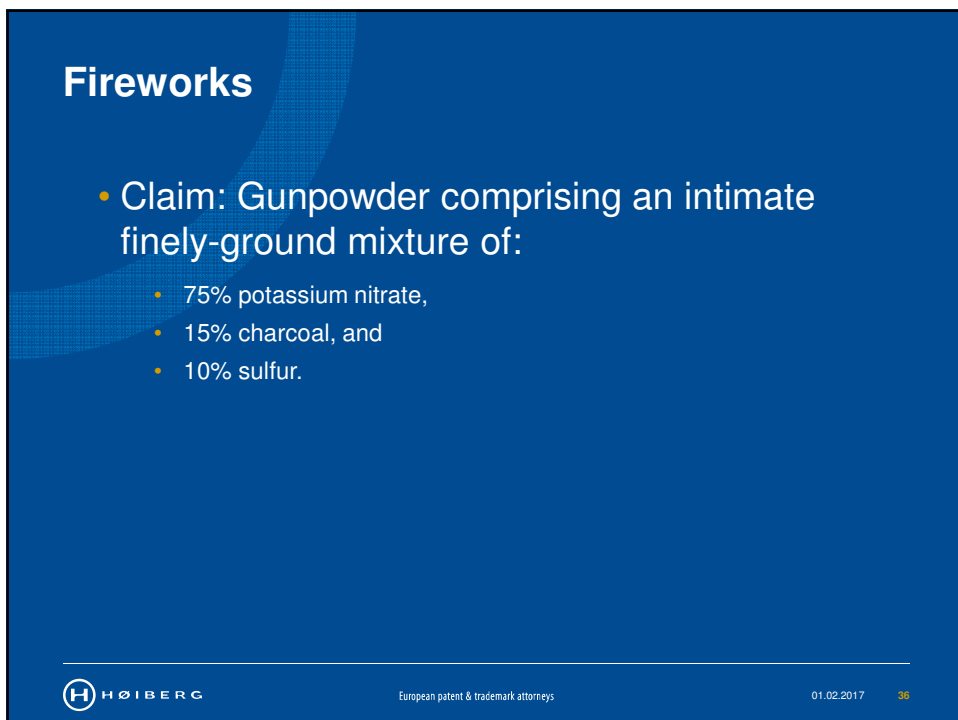


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European patent & trademark attorneys

01.02.2017 95



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European patent & trademark attorneys

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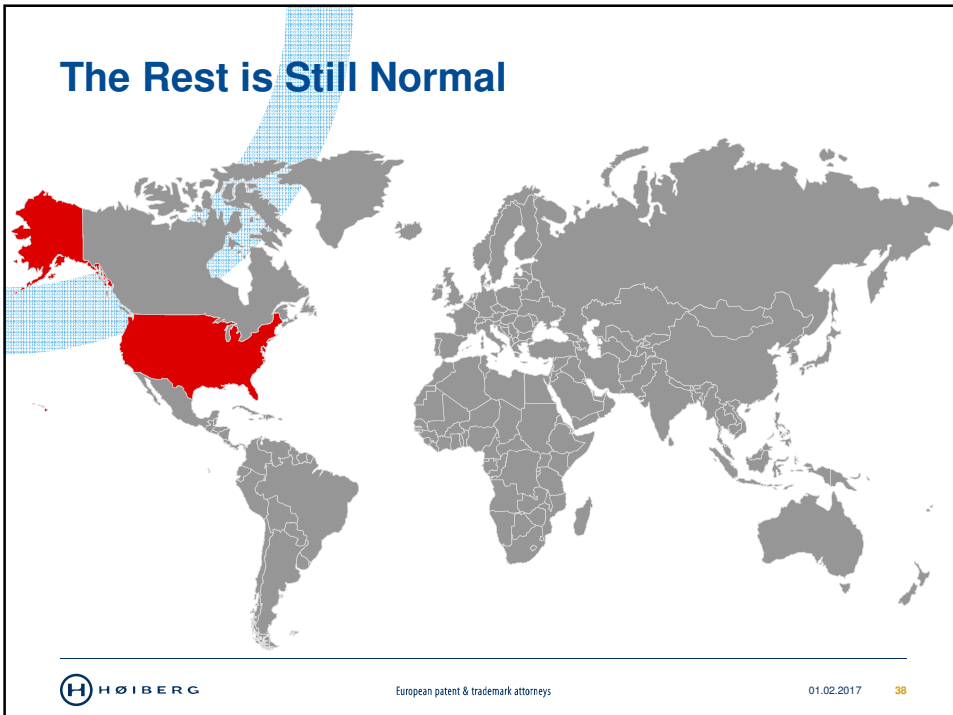
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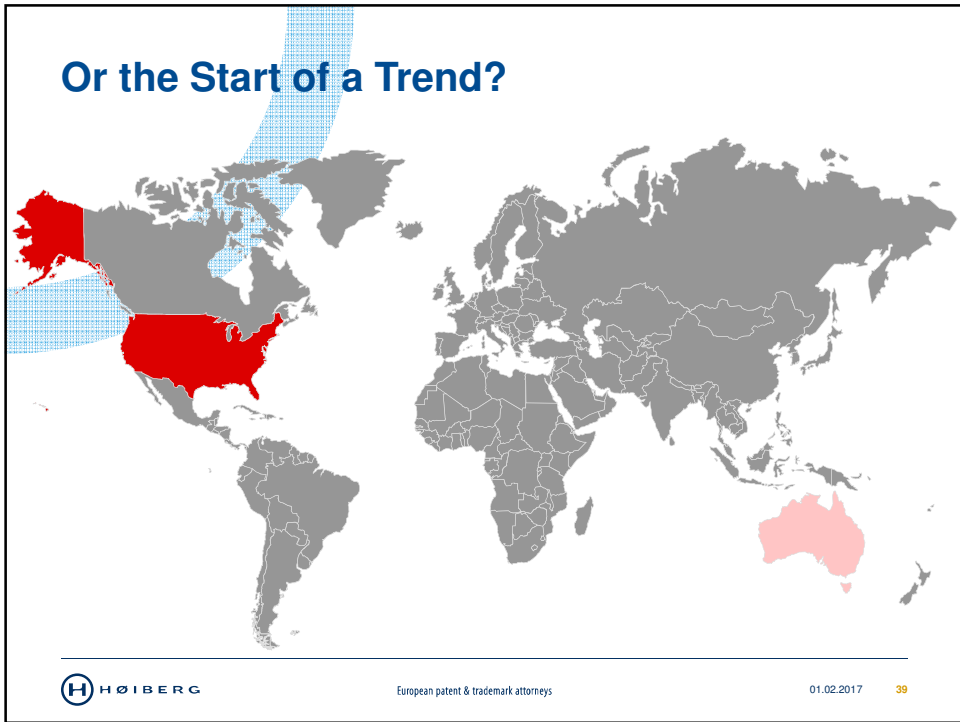
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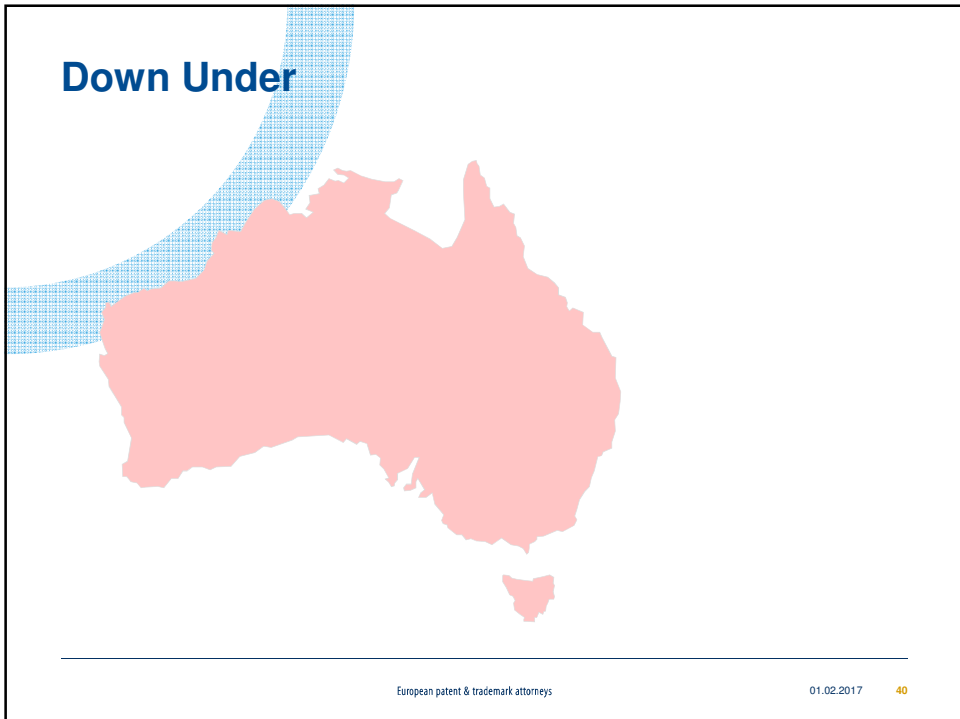
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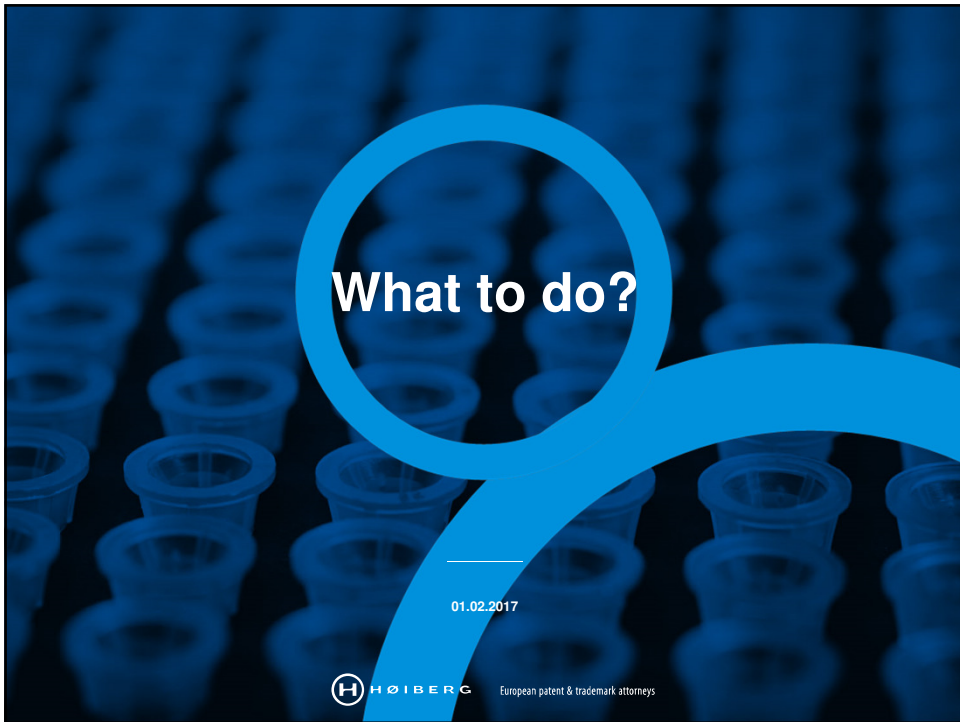
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University of Copenhagen

jvn@hoiberg.com

 HØIBERG European patent & trademark attorneys 01.02.2017

Agenda

Stem cells
Plant varieties
Products of nature
Laws of nature
Abstract ideas

Why Exceptions



- Ethics, morale
- Non-technical
- Alternative types of protection
- Courts' interpretation of the law
- Public/lobbyist pressure

East meets West

USA

Common law country

Governed by

- the law
- Court interpretation

Europe

Legislator decides

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- Ethics
- No double protection

Stem cells (European Exemption)

- The law:
- No patents on:
 - Processes for cloning human beings
 - Processes for modifying the germ line genetic identity of human beings
 - Uses of human embryos for industrial or commercial purposes

Stem Cells

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- Patents on stem cells are invalid if generation of stem cells require “destruction of human embryos”

Light at the end of the Tunnel?

- Stem cells can be generated by single-cell biopsy from embryo.
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Plant Varieties

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Plant Varieties - Background

New plant varieties can be Protected (UPOV; CPVO)

European exception

Breeder's & farmer's privilege

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European patent & trademark attorneys
01.02.2017 10

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- Patents are not granted on plant and animal varieties.
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Plant Varieties – European Status

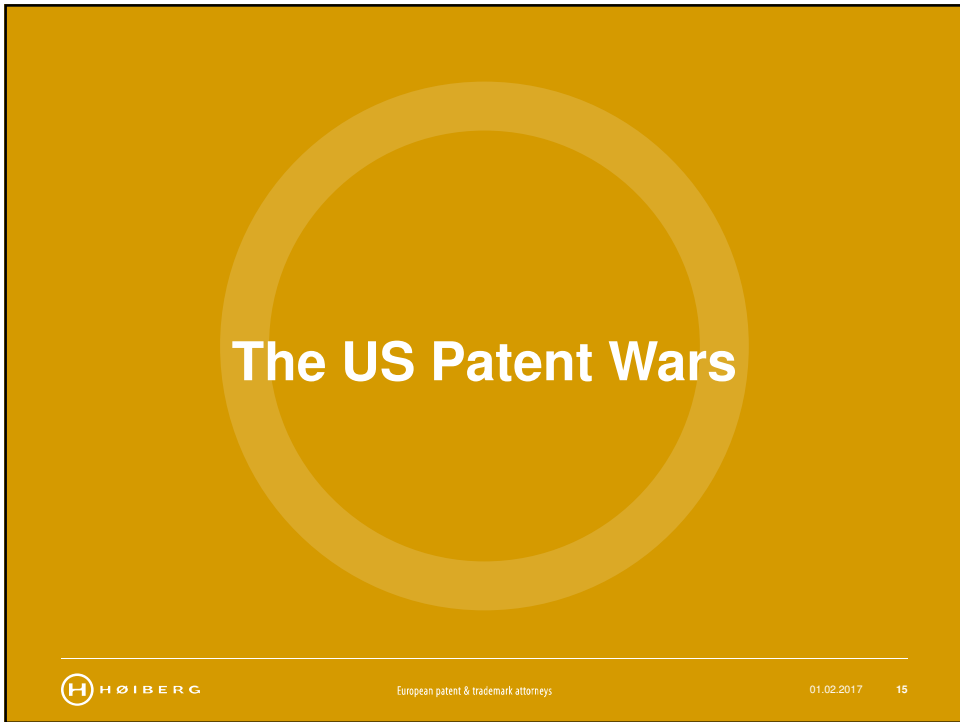
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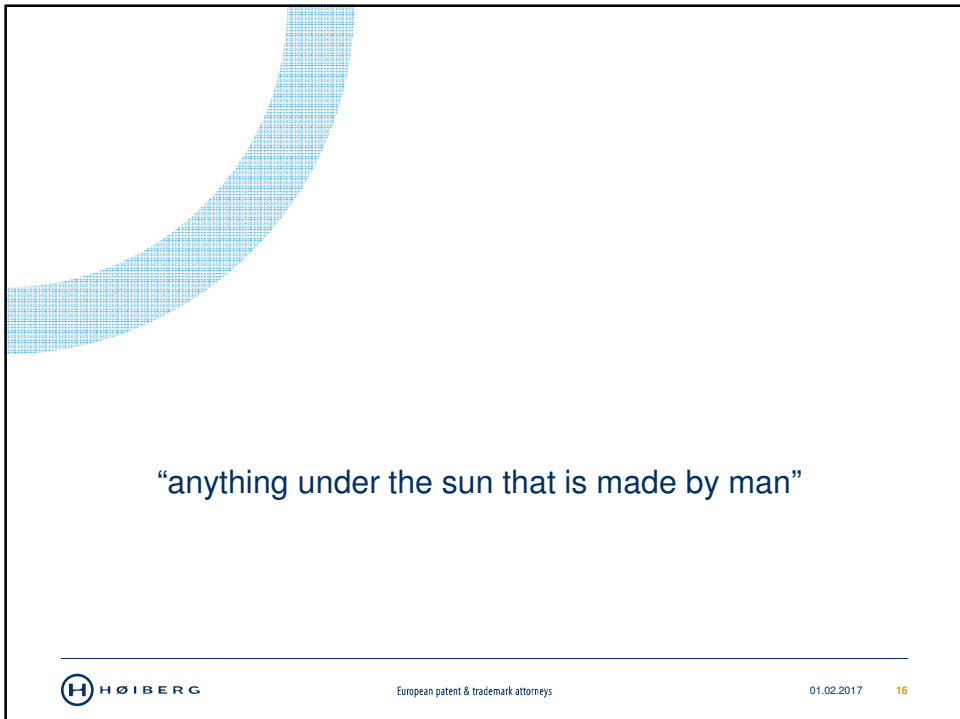
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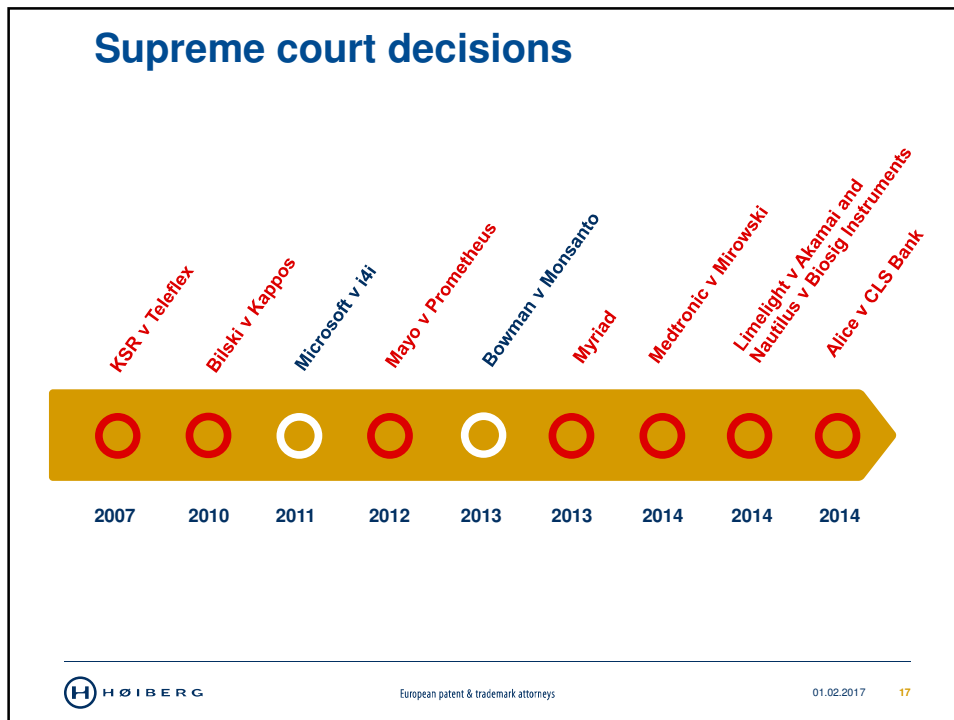
The US Patent Wars

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“anything under the sun that is made by man”

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What does the law say

Patent eligible subject matter (§ 101):
 Whoever invents or discovers any new and useful
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machine,
manufacture, or
composition of matter, or
 any new and useful improvement thereof, may obtain a patent
 therefor, subject to the conditions and requirements of this title.

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Mayo vs. Prometheus

- Prometheus Labs had rights to a series of US patents directed to a diagnostic method.
- The method involved:
 - Determining the level of metabolites of thiopurines
 - Wherein the level indicates a need to increase or decrease the amount of drug to be administered.
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- No diagnostic patents are granted
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Myriad

- Myriad Genetics proprietor to a number of US patents
- Patent claims:
 - "isolated" human deoxyribonucleic acid (DNA) sequences "BRCA1" and "BRCA2"; and
 - mutations associated with predisposition to breast and ovarian cancers

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Myriad

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- It is important to note what is *not* implicated by this decision.
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- Patentability of DNA in which the order of the naturally occurring nucleotides has been altered was not considered (cDNA).



Myriad - Consequences

- No patents on naturally occurring products
- Recombinant proteins
- Small molecules
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- Stem cells
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Living next door to – Alice Corp

*Alice v. CLS Bank Supreme Court Case
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Claim 18. A method to enable the formulation of customized multi-party risk management contracts having a future time of maturity, the method comprising the steps of:

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Many diagnostic algorithms fail the Alice test

Examples from Guidelines and Training materials

- Amazonic acid (anticancer drug from plant)
- Pomelo juice with preservative
- Gunpowder

Amazonic acid background

Amazonian cherry tree grows wild in Amazonas

It's leaves contain a substance that has anti-cancer effects

Nobody has succeeded in isolating the compound

Amazonic acid background

Applicant has isolated amazonic acid

Has demonstrated effect in treatment of breast and colon cancer

Has created deoxy amazonic acid, with same activity as amazonic.

Amazonic acid

- Claim 1: Purified amazonic acid
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Patentability Assessment

Claim 1 is not patentable. Separating the acid from its surrounding material in the leaf has resulted in the purified amazonic acid having not markedly different characteristics from its naturally occurring counterpart.

Claim 2 is patentable. The 5-methyl does not exist in nature. The change in structure has not resulted in any different functional characteristics. However, it is patentable because deoxyamazonic acid is a unique molecule that is distinct from, and does not prevent others from using, naturally occurring amazonic acid.

Claim 3 is patentable. The claim is focused on a process of practically applying the product to treat a particular disease (breast or colon cancer), and not on the product *per se*.

Pomelo Juice

1. A composition comprising pomelo juice, and a an effective amount of a preservative.
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Claim 1: Patentable. the preservative affects the juice so that it spoils much more slowly (spoil in a few weeks) than the naturally occurring juice by itself (spoil in a few days).

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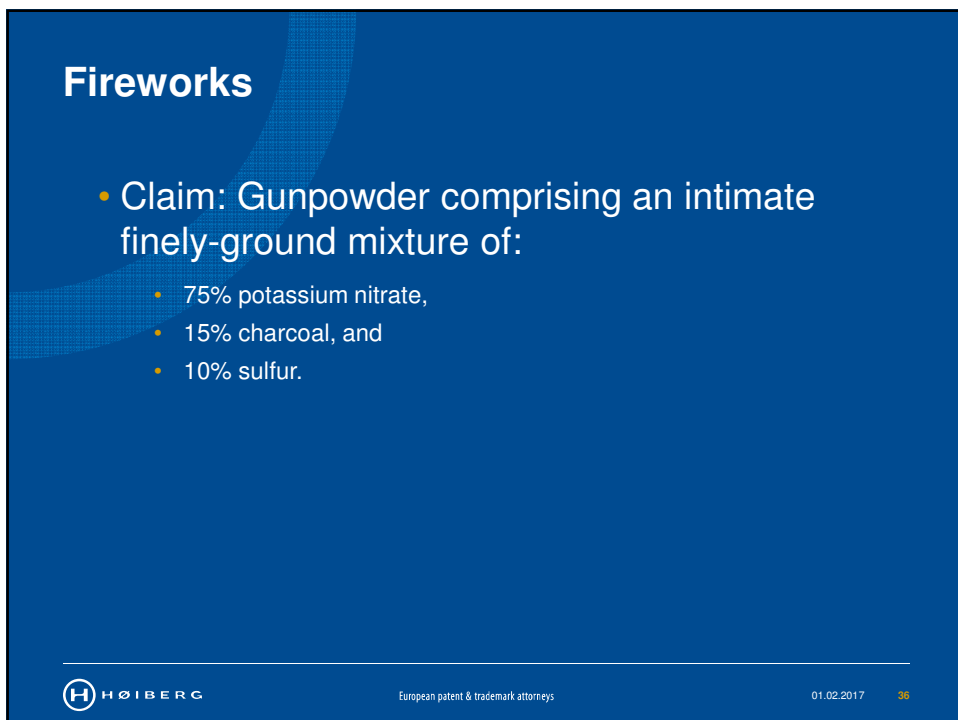


Gunpowder

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Fireworks

- Claim: Gunpowder comprising an intimate finely-ground mixture of:
 - 75% potassium nitrate,
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We have an Invention!

This claim is patentable.

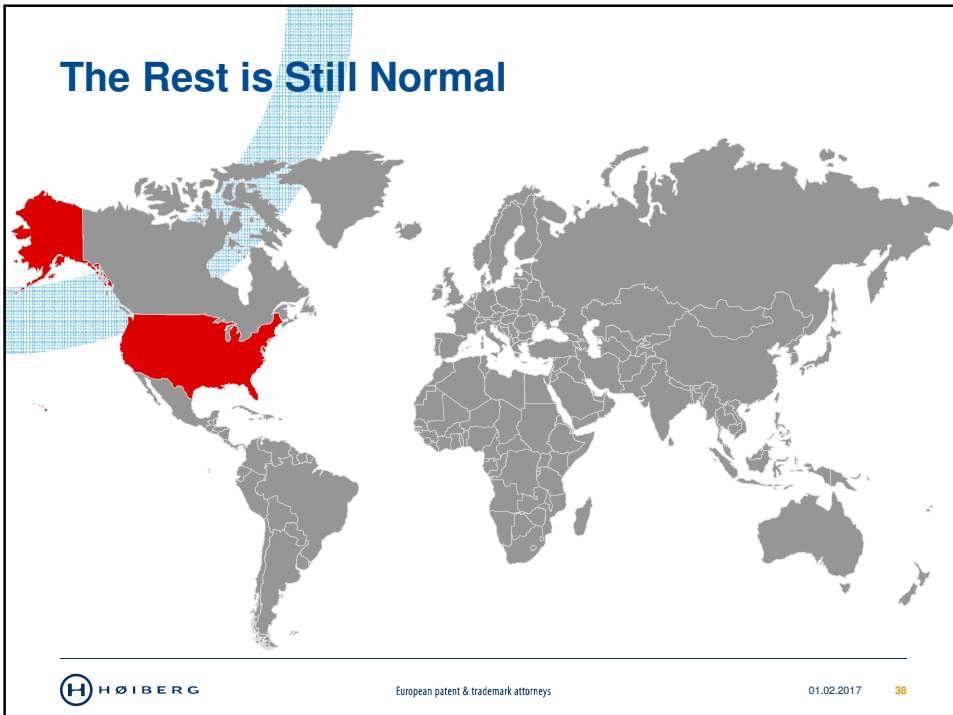
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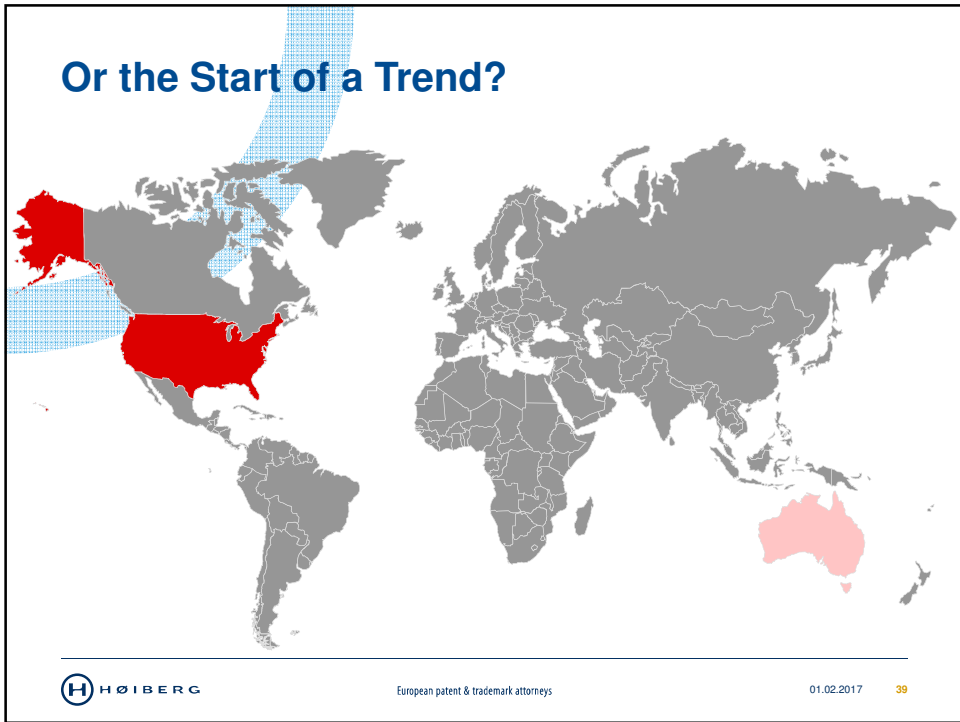
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Or the Start of a Trend?



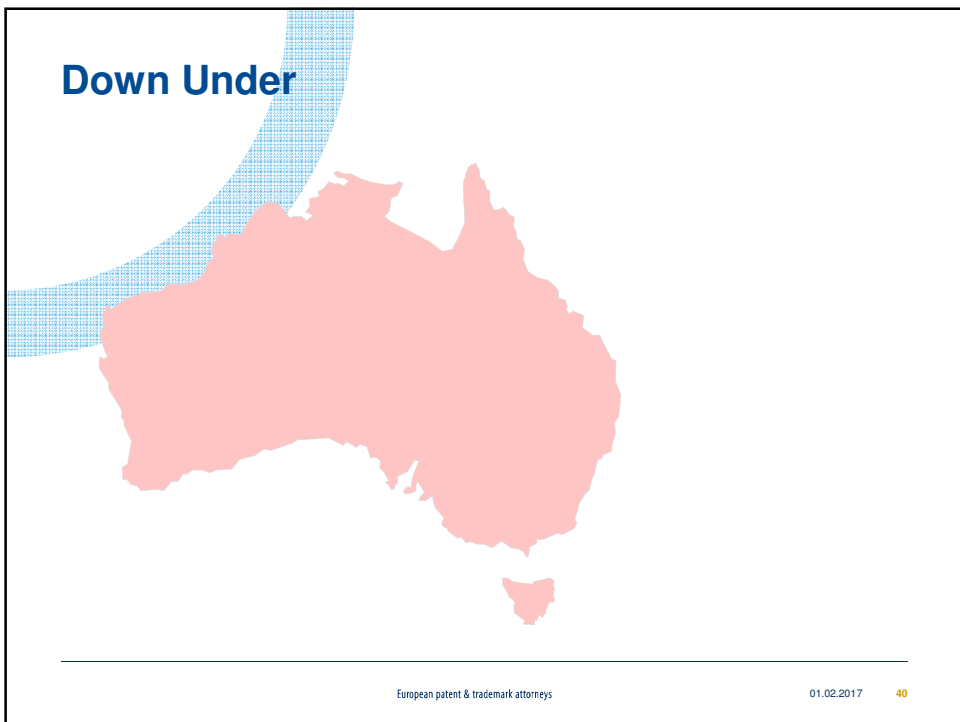
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Down Under



A map of Australia and its territories, highlighted in red. A blue shaded area is visible on the left side of the map.

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Recent Decision from AU High Court


- Myriad Genetic's Australian patent on BRCA1 and BRCA2 mutations.
- Claims to isolated DNA: not patentable
- Vectors, probes: patentable
- Diagnostic methods: patentable

Guidance from AU Patent Office

- Proteins and peptides are patentable
- Isolated small molecules (amazonic acid) are patentable
- Diagnostic methods are patentable
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Diagnostics


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Diagnostics

Focus on new and patentable analytical methods

Measure the marker using MS, HPLC or similar "high tech"

Recite all steps of analytical method (e.g. PCR, Elisa)

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Tie the diagnostic method to treatment, follow-on diagnostics

e.g. add a method of treatment step at the end (if tested positive for condition X, treat with drug Y)

Argue that the additional steps are not routine and conventional. If the claim is non-obvious, it should be patentable.

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Do not look for mutants/derivatives in nature

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Other Exceptions in General

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- No patents on plants, seeds, or animals
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Exceptions to Patentability

What cannot be done

Jens Viktor Nørgaard
01.02.2017

 HØIBERG European patent & trademark attorneys

Speaker / CV



Jens Viktor Nørgaard

Head of Biotechnology & Plant sciences
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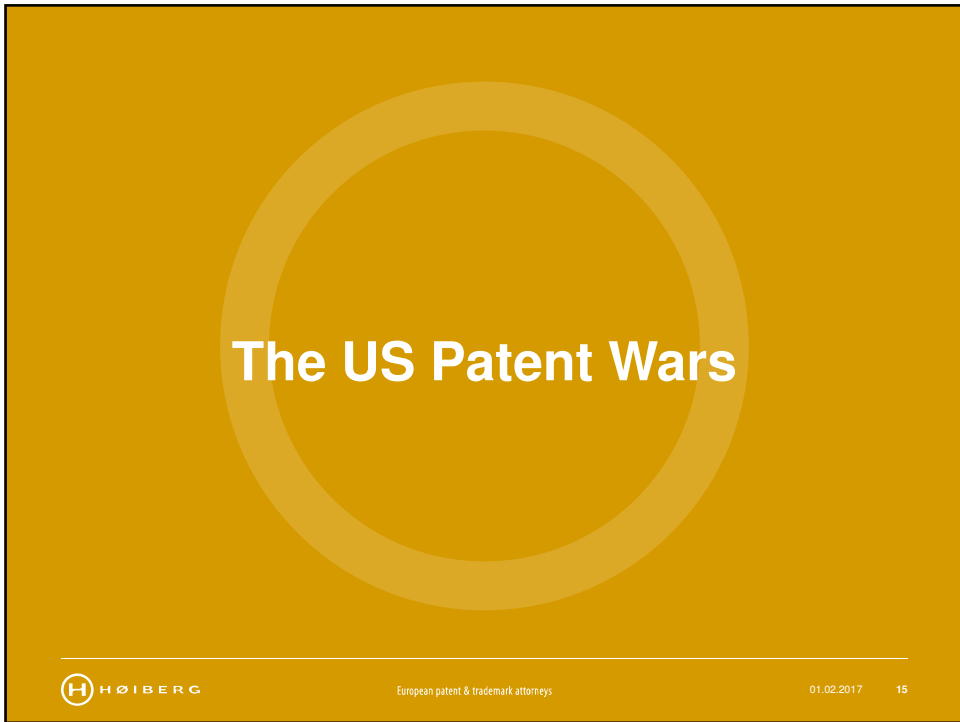
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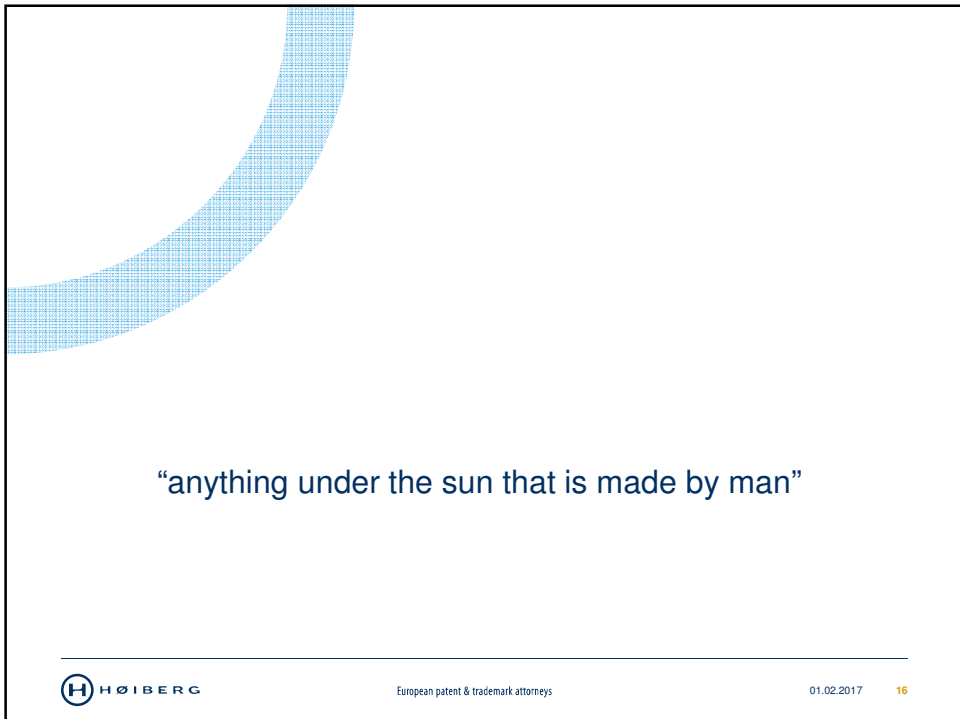
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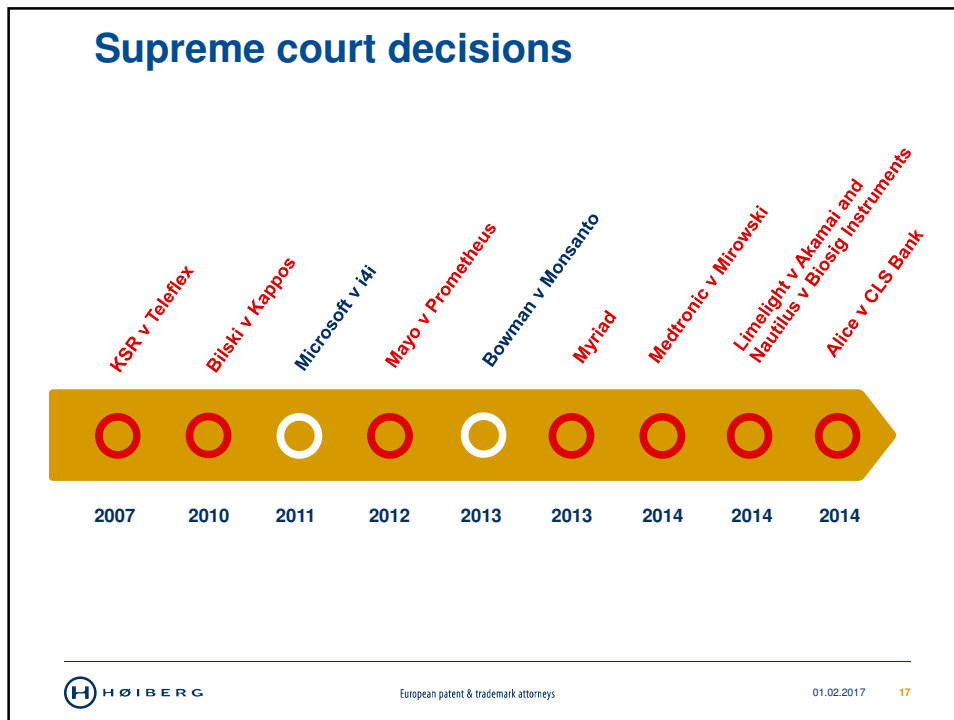
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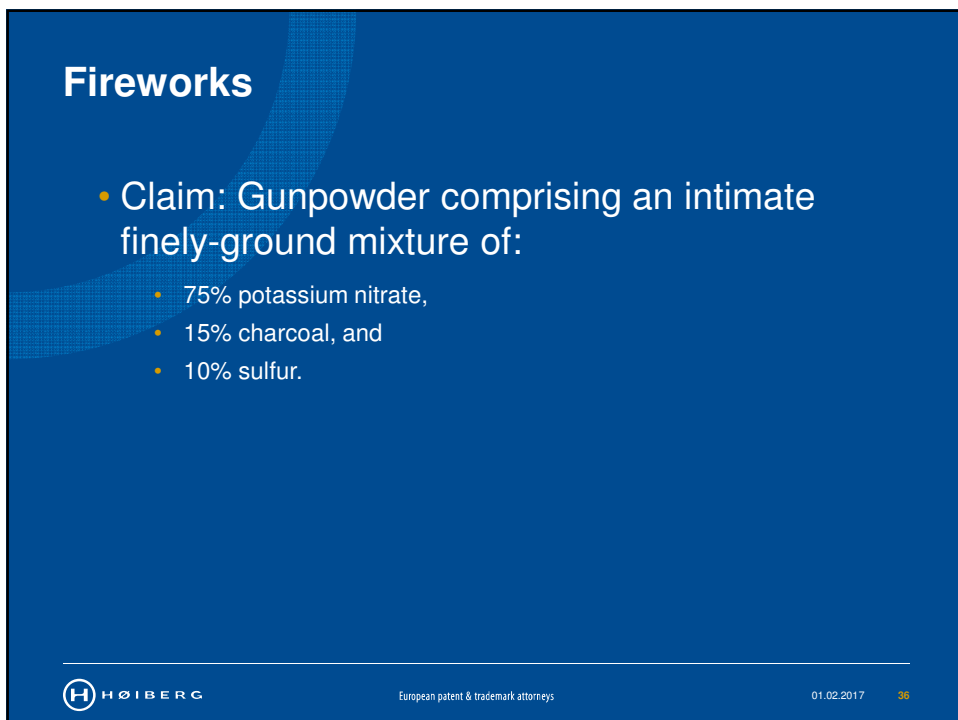
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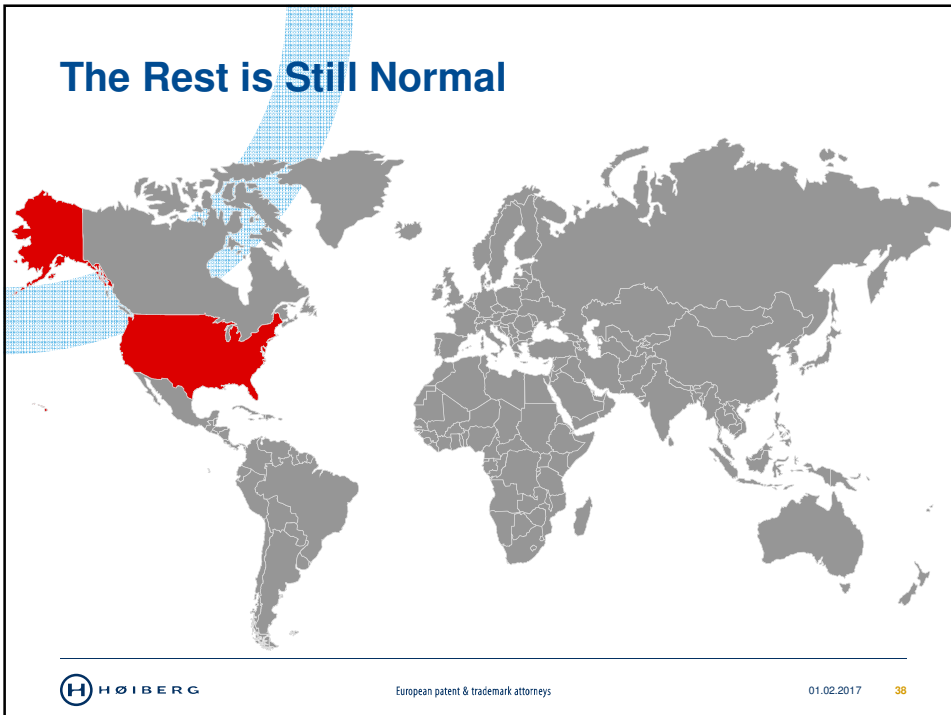
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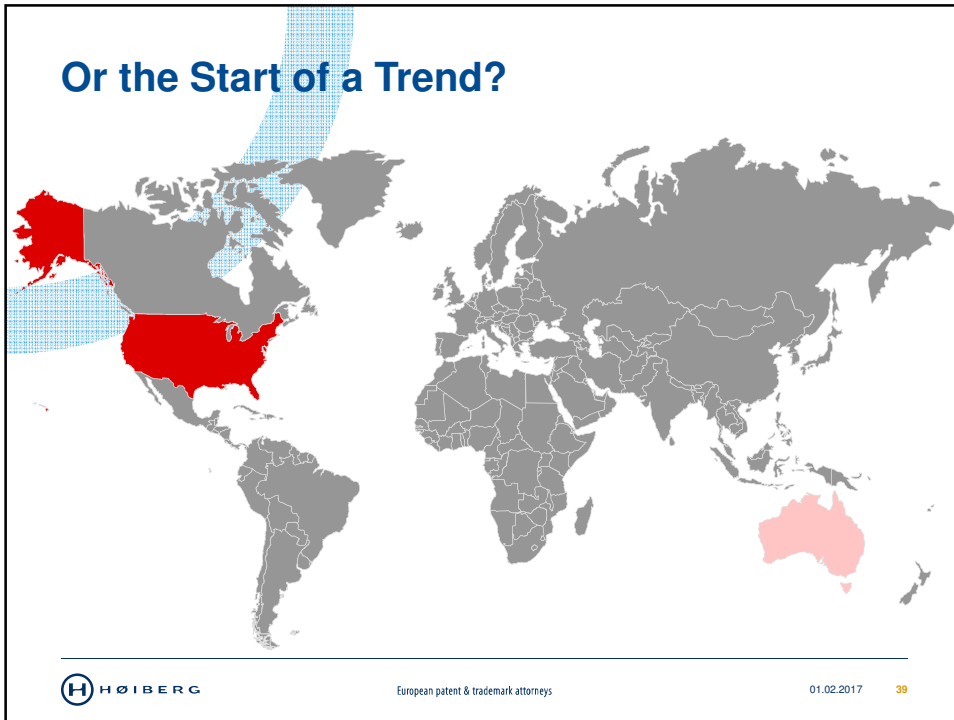
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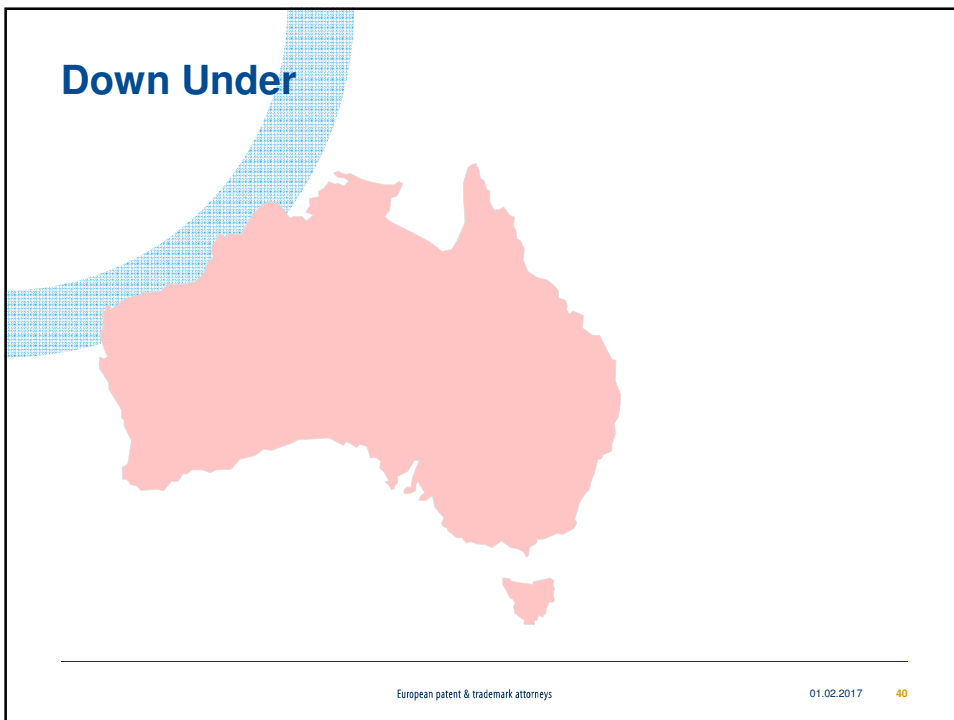
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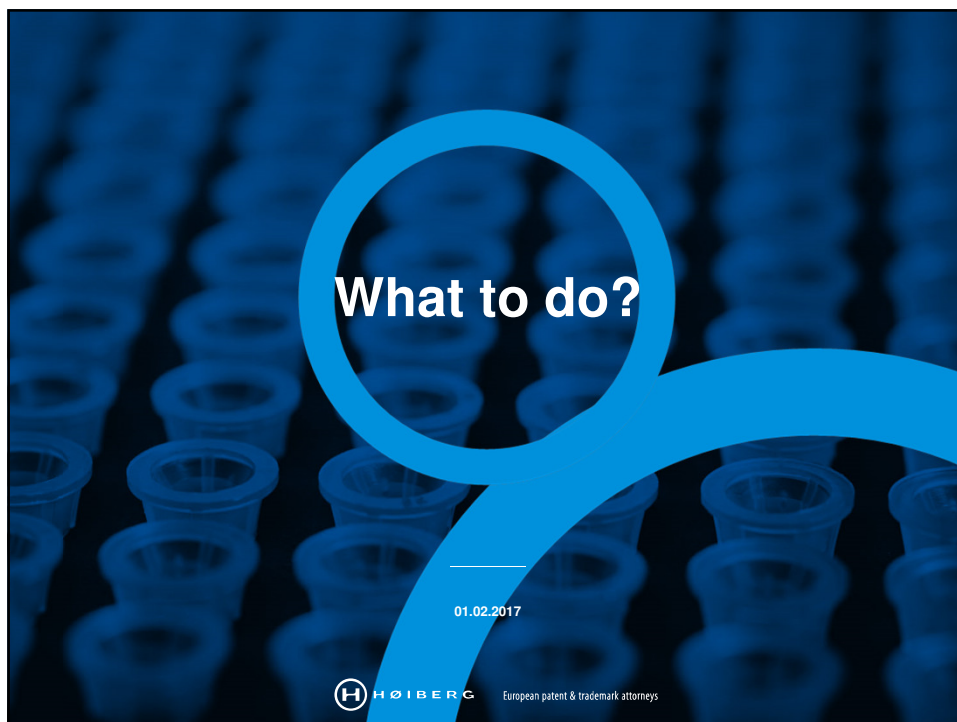
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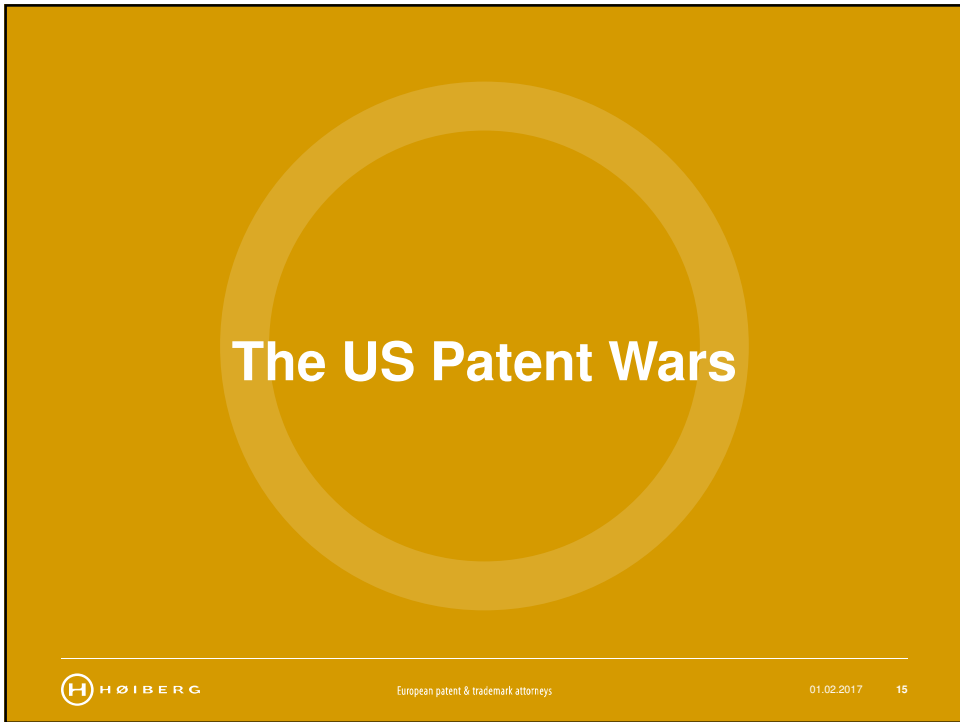
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European Status – or perhaps not

- European Commission has interpreted the “intention” of the legislator of the Biotech Directive.
- According to the Commission, the intent was not to allow patents on plant or animal varieties obtained by “essentially biological processes”.
- EPO has stayed proceedings in all relevant cases....
- Stay tuned

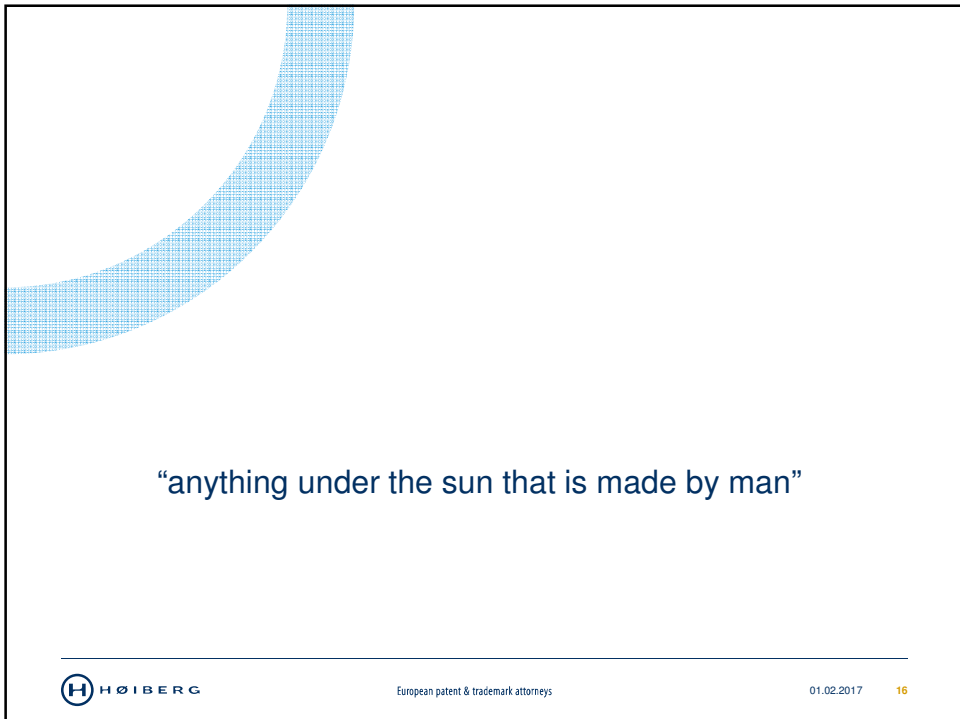
Europe – lack of Harmonisation

- Different rights floating from plant patents
- Holland: The breeder has a right to a license to “Plant patents”
- Germany: Complete freedom to use patented plants for breeding
- Denmark, etc: no special rights for plant breeders




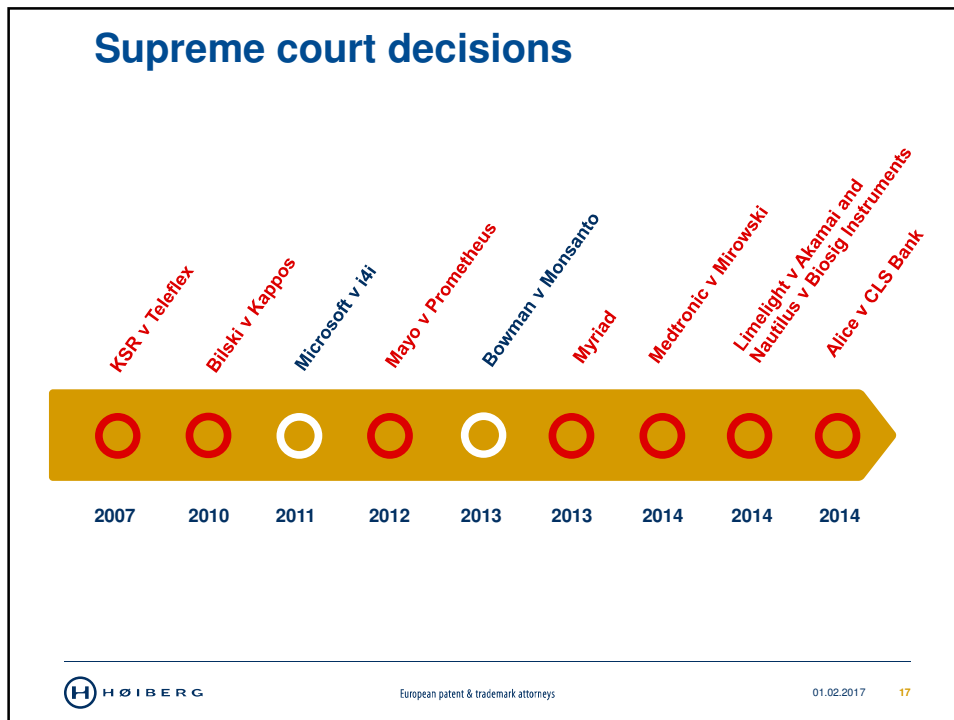
The US Patent Wars

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“anything under the sun that is made by man”

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What does the law say

Patent eligible subject matter (§ 101):
 Whoever invents or discovers any new and useful
process,
machine,
manufacture, or
composition of matter, or
 any new and useful improvement thereof, may obtain a patent
 therefor, subject to the conditions and requirements of this title.

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Mayo vs. Prometheus

- Prometheus Labs had rights to a series of US patents directed to a diagnostic method.
- The method involved:
 - Determining the level of metabolites of thiopurines
 - Wherein the level indicates a need to increase or decrease the amount of drug to be administered.
- Prometheus sued Mayo Medical Laboratories for infringement of their US patents

Mayo vs. Prometheus


There is a danger that granting patents that tie up use of laws of nature will inhibit future innovation

Provides incentives that lead to creation, invention and discovery

Patent protection is a two-edged sword


Consequences

- No diagnostic patents are granted
- Diagnostic correlation = "law of nature"
- The detection method must be patentable in itself

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Myriad

- Myriad Genetics proprietor to a number of US patents
- Patent claims:
 - "isolated" human deoxyribonucleic acid (DNA) sequences "BRCA1" and "BRCA2"; and
 - mutations associated with predisposition to breast and ovarian cancers

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Myriad

- Supreme Court Held that “isolated” stretches of genomic DNA for the BRCA1 gene were not patent eligible
- Products of nature (despite acknowledged chemical differences)
- Groundbreaking, innovative, or even brilliant discovery is not by itself sufficient



Myriad

- It is important to note what is *not* implicated by this decision.
- This case does not involve patents on new *applications* of knowledge about the BRCA1 and BRCA2 genes.
- Patentability of DNA in which the order of the naturally occurring nucleotides has been altered was not considered (cDNA).



Myriad - Consequences

- No patents on naturally occurring products
- Recombinant proteins
- Small molecules
- Microorganisms
- Stem cells
- Dolly the sheep



Living next door to – Alice Corp

*Alice v. CLS Bank Supreme Court Case
Business Method patent.*

Claim 18. A method to enable the formulation of customized multi-party risk management contracts having a future time of maturity, the method comprising the steps of:

Question – is the patent directed to an abstract idea and nothing more

The Alice Test

1) Are the claims directed to a patent-ineligible concept (*e.g.*, an abstract idea)?

2) If so, what else is there in the claim?

• This step is a search for an “inventive concept”—*i.e.*, an element or combination of elements that is “sufficient to ensure that the patent in practice amounts to “significantly more” than a patent upon the [ineligible concept] itself.”

Many diagnostic algorithms fail the Alice test

Examples from Guidelines and Training materials

- Amazonic acid (anticancer drug from plant)
- Pomelo juice with preservative
- Gunpowder

Amazonic acid background

Amazonian cherry tree grows wild in Amazonas

It's leaves contain a substance that has anti-cancer effects

Nobody has succeeded in isolating the compound

Amazonic acid background

Applicant has isolated amazonic acid

Has demonstrated effect in treatment of breast and colon cancer

Has created deoxy amazonic acid, with same activity as amazonic.

Amazonic acid

- Claim 1: Purified amazonic acid
- Claim 2: Deoxyamazonic acid.
- Claim 3: A method of treating breast or colon cancer, comprising: administering an effective amount of purified amazonic acid to a patient suffering from breast or colon cancer.

Patentability Assessment

Claim 1 is not patentable. Separating the acid from its surrounding material in the leaf has resulted in the purified amazonic acid having not markedly different characteristics from its naturally occurring counterpart.

Claim 2 is patentable. The 5-methyl does not exist in nature. The change in structure has not resulted in any different functional characteristics. However, it is patentable because deoxyamazonic acid is a unique molecule that is distinct from, and does not prevent others from using, naturally occurring amazonic acid.

Claim 3 is patentable. The claim is focused on a process of practically applying the product to treat a particular disease (breast or colon cancer), and not on the product *per se*.

Pomelo Juice

1. A composition comprising pomelo juice, and a an effective amount of a preservative.
2. The composition of claim 1 wherein the preservative is 0.5% vitamin E.
3. The composition of claim 1 wherein the pomelo juice is pasteurized.

Pomelo Juice

Claim 1: Patentable. the preservative affects the juice so that it spoils much more slowly (spoil in a few weeks) than the naturally occurring juice by itself (spoil in a few days).

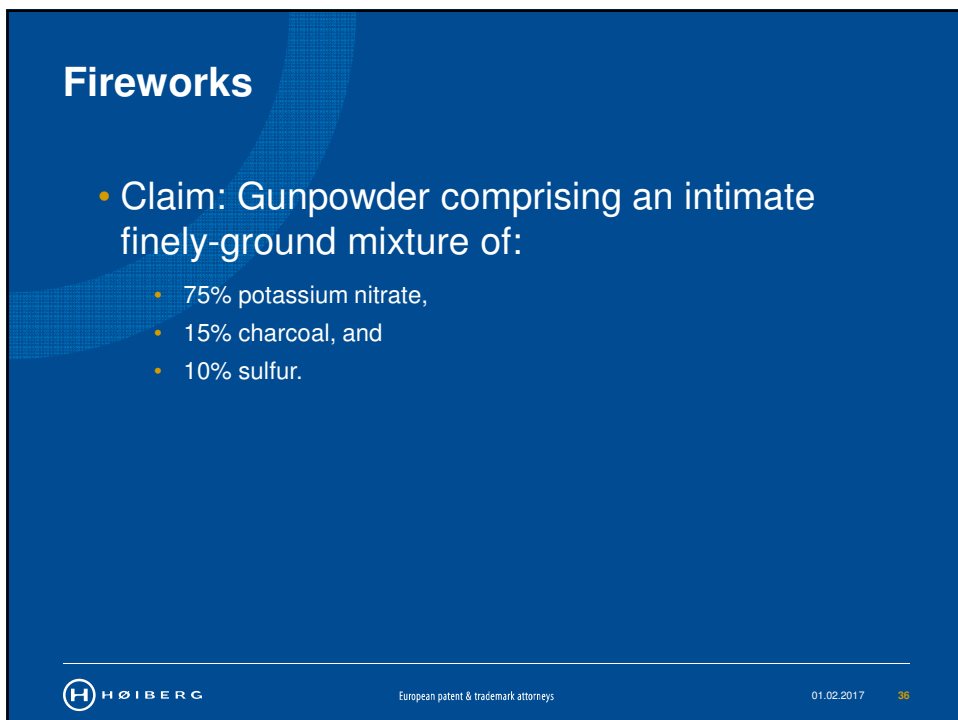
Claim 2: passes the test. X does not occur in nature.

Claim 3: passes the test because the description explains that pasteurizing the juice changes the chemical composition (and uses a big machine)




Gunpowder

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Fireworks

- Claim: Gunpowder comprising an intimate finely-ground mixture of:
 - 75% potassium nitrate,
 - 15% charcoal, and
 - 10% sulfur.

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We have an Invention!

This claim is patentable.

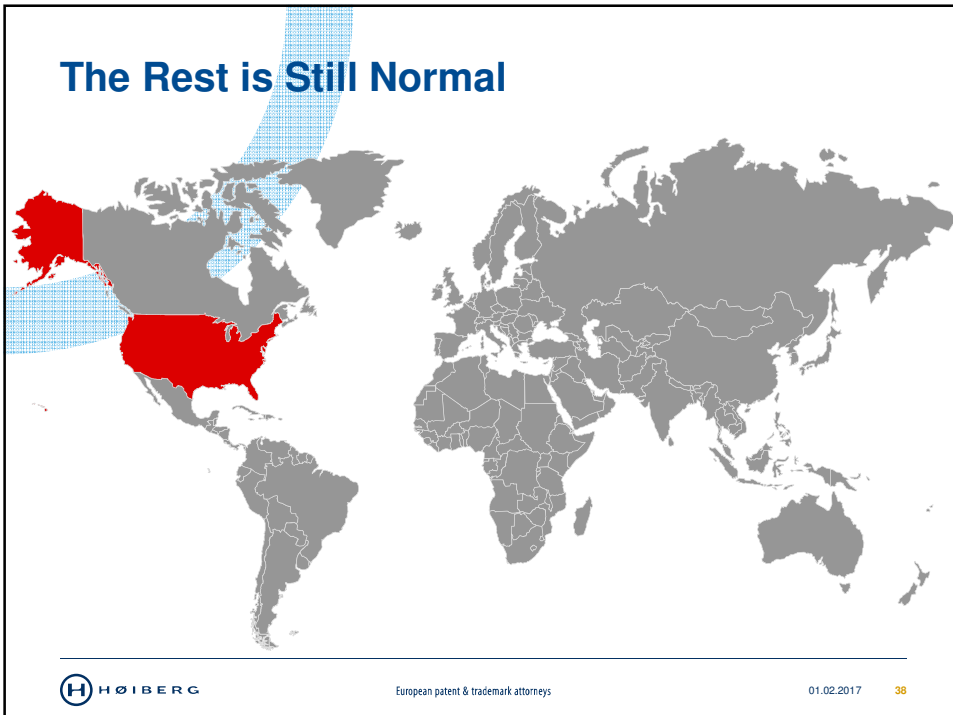
Look at the combination.

The components do not occur together in nature.

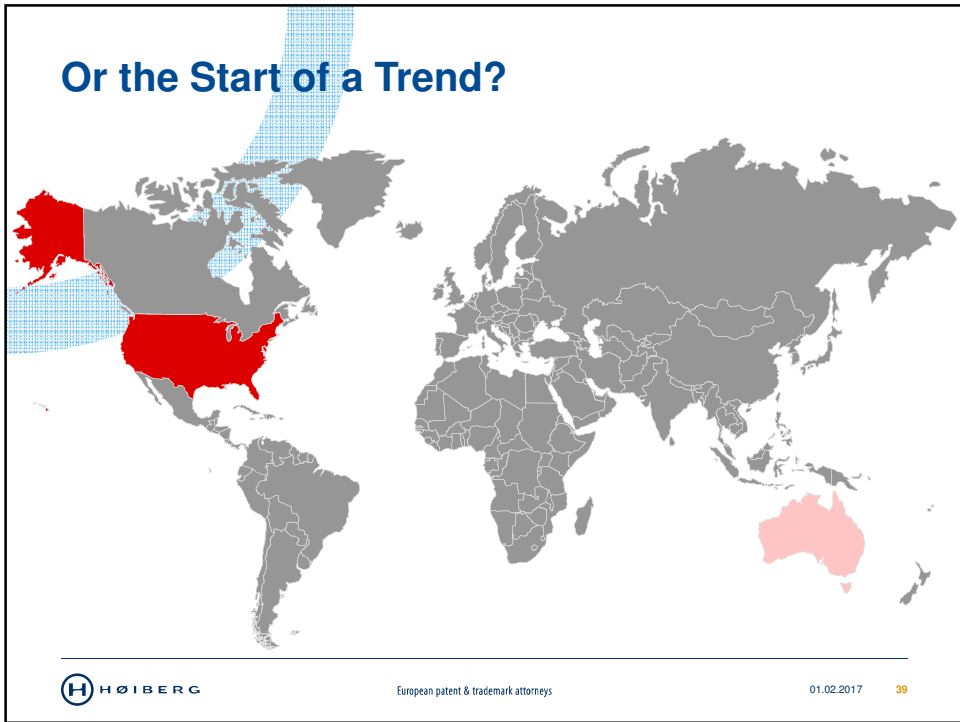
None of the three claimed substances are explosive in nature.

This explosive property of the claimed combination is markedly different from the non-explosive properties of the substances by themselves in nature

The Rest is Still Normal



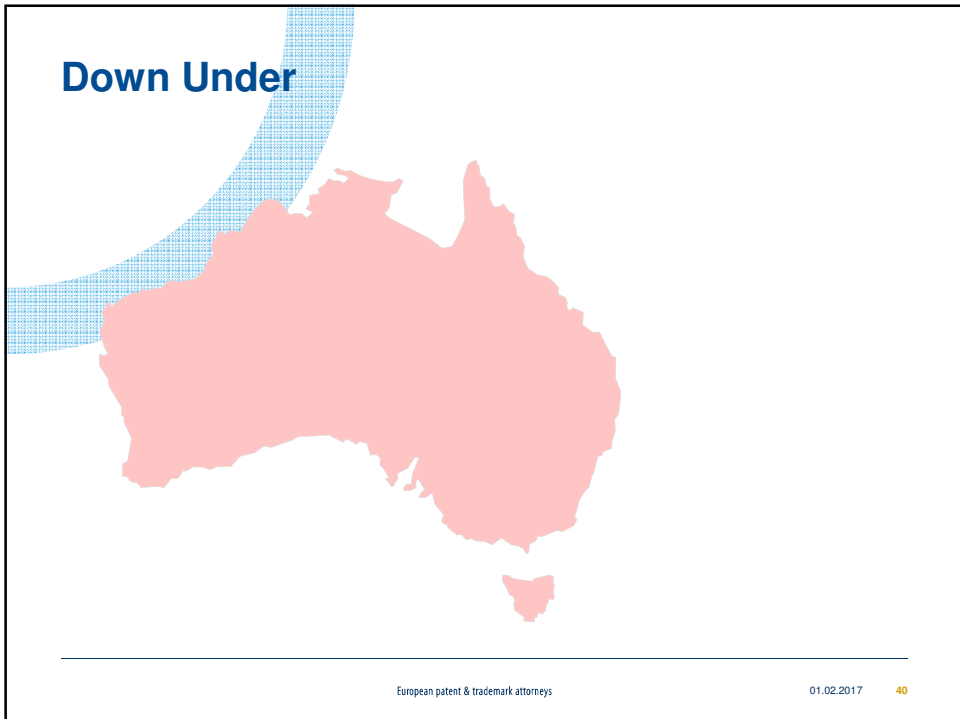
Or the Start of a Trend?



A world map where the United States, Australia, and parts of Europe (including the UK and France) are highlighted in red. A blue curved arrow points from the top left towards the center of the map.

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Down Under



A map of Australia and its territories, highlighted in red. A blue curved arrow points from the top left towards the map.

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Recent Decision from AU High Court


- Myriad Genetic's Australian patent on BRCA1 and BRCA2 mutations.
- Claims to isolated DNA: not patentable
- Vectors, probes: patentable
- Diagnostic methods: patentable

Guidance from AU Patent Office

- Proteins and peptides are patentable
- Isolated small molecules (amazonic acid) are patentable
- Diagnostic methods are patentable
- Methods of treatment are patentable



Diagnostics


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Diagnostics

Focus on new and patentable analytical methods

Measure the marker using MS, HPLC or similar "high tech"

Recite all steps of analytical method (e.g. PCR, Elisa)

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Diagnosis

Tie the diagnostic method to treatment, follow-on diagnostics

e.g. add a method of treatment step at the end (if tested positive for condition X, treat with drug Y)

Argue that the additional steps are not routine and conventional. If the claim is non-obvious, it should be patentable.

Compound patents

Compound patents

Add synthesis claims – recombinant or synthetic

Add mutant/derivative/conjugate claims

Do not look for mutants/derivatives in nature

Add method of treatment claims

Other Exceptions in General

- Business methods
- Computer programs "as such"

India

- No patents on plants, seeds, or animals
- No patents on drug formulations
- No patents on salts
- No patents on new use of known compound
- No patents on products isolated from nature

**Thank you
for your
attention**