

Immaterielle rettigheter

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En serie webinarer,
fra grunnleggende innsikt
til IP-strategi

Del 3

12. mai 2021

14:00-15:00

**Freedom to operate –
kjenne konkurrenter
og eget handlingsrom**

Arrangør:



Norwegian Centre of Expertise
NCE Blue Legasea



Biotech North[®]

I samarbeid med:

BRYN AARFLOT

1947

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1947

FREEDOM TO OPERATE

KJENNE KONKURRENTER OG EGET HANDLINGSROM

12. MAI 2021

BRYN AARFLOT

EST 1947

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Arrangør:



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Isamarbeid med:

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1947



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BRYN AARFLOT

EST. 1947

Norway's leading full-service IP firm

IPR | Commercialization | Dispute Resolution

Our legal and technical services cover all aspects of trademarks, patents, designs, copyrights, domain names and unfair competition



Overview

Introduction

What “Freedom to operate (FTO)” means

Why you should have it

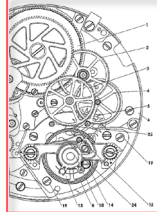
How and When to check if you have FTO

How to obtain FTO

Cases

Conclusions

From webinar 1: IP rights



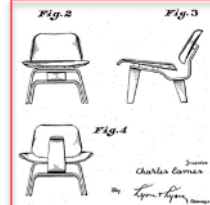
Patents

- Technical inventions
- Solutions to technical problems



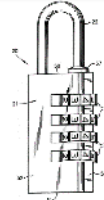
Trademarks

- Company names, product names, logos, etc.



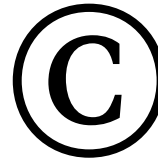
Designs

- Aesthetic, non-technical looks/shapes/forms



Trade secrets

- Information that is and should be kept secret

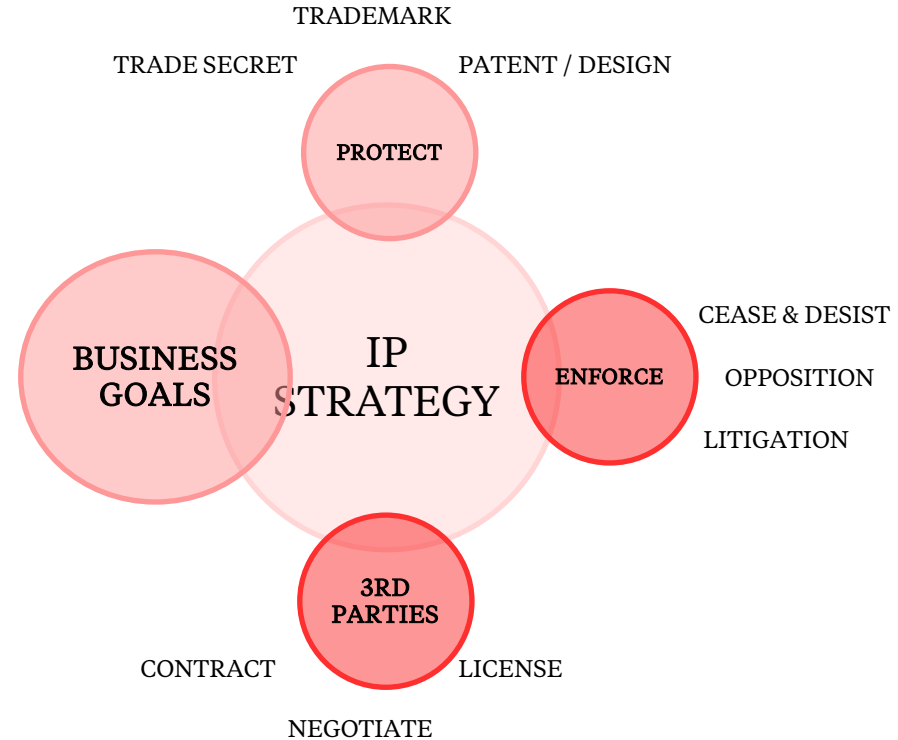


Copyright

- Original creative works

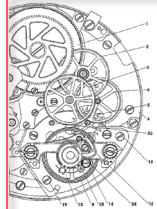
From webinar 2: From protection to commercialisation

- Your IP portfolio is a tool to reach your business goals
- Develop IP and implement strategy based on business model and goals; review and update regularly; make sure to follow it
- Tailor IP portfolio to suit your needs; do not be afraid to downsize
- Approach IP holistically



What does «freedom to operate» mean?

Respecting third party rights



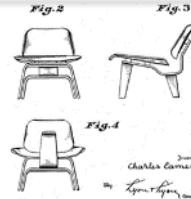
Patents

- Technical inventions
 - Solutions to technical problems
- LEGAL DOCUMENT THAT
- Gives the **owner the right to exclude other** from gaining from the invention
 - Limited time periode
 - Territorial right



Trademarks

- Company names, product names, logos, etc.



Designs

- Aesthetic, non-technical looks/shapes/forms

What does “freedom to operate” mean?

- Legal perspective: To have «assembled» all the IP rights for a specific **product** for a specific **market** and specific **use**.
- Business perspective: A **product development** and **risk** management strategy

To ensure that commercial production, marketing and use of a product, process and use do not infringe IP rights of others

FTO = you can make, use, sell your technology without infringing third party IP

Why FTO analyses should be done

- Necessary part of strategy and plan to address company's valuable assets
- To identify and develop your position in R&D and market
- Identify patents that may impact your plan - **Reduce risks**
- Analysing the patent landscape can assist you with defining directions for R&D
- Mapping out your freedom-to-operate before development/launch provides valuable predictability and mitigates the risk of expensive (and possibly embarrassing) infringement claims from third parties
- As **investment opportunity**, investors want:
 - Technology that works with **solid IP position**: protected assets + **FTO**
 - Dedicated team, sizeable market, unmet need, regulatory clarity
- Company value, ability to generate revenue: closely tied to IP position

Infringement damages

[2018-pwc-patent-litigation-study.pdf \(ipwatchdog.com\)](https://www.ipwatchdog.com/resources/reports-studies/2018-pwc-patent-litigation-study.pdf)

Top ten largest initial adjudicated damages awards: 1998–2017

Fig 2

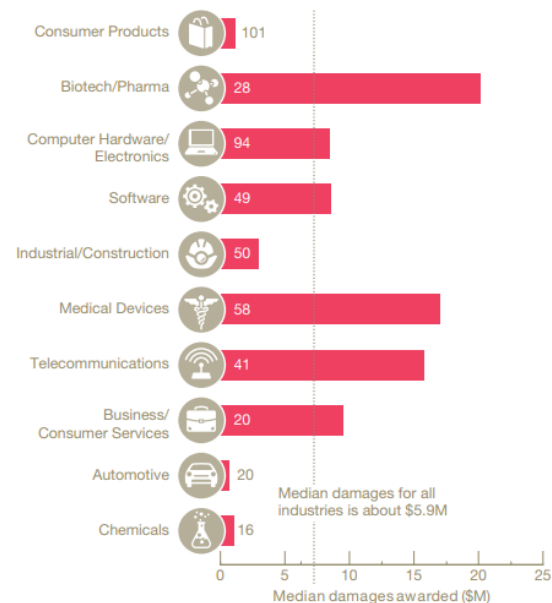
Idenix (Merck) v. Gilead remains the largest initial damages award, although it was reversed by the District Court in February 2018. No awards in 2017 breached the top ten.

Year	Plaintiff	Defendant	Technology	Award (in \$M)
2016	Idenix Pharmaceuticals	Gilead Sciences Inc.	Hepatitis C drugs	\$2,540
2009	Centocor Ortho Biotech Inc.	Abbott Laboratories	Arthritis drugs	\$1,673
2007	Lucent Technologies Inc.	Microsoft Corp.	MP3 technology	\$1,538
2012	Carnegie Mellon University	Marvell Technology Group	Noise reduction on circuits for disk drives	\$1,169
2012	Apple Inc.	Samsung Electronics Co.	Smartphone software	\$1,049
2012	Monsanto Company	E.I. Du Pont De Nemours and Co.	Genetically modified soybean seeds	\$1,000
2005	Cordis Corp.	Medtronic Vascular, Inc.	Vascular stents	\$595
2015	Smartflash LLC	Apple Inc.	Media storage	\$533
2004	Eolas Technologies Inc.	Microsoft Corp.	Internet browser	\$521
2011	Bruce N. Saffran M.D.	Johnson & Johnson	Drug-eluting stents	\$482

Median damages award: Top ten industries: 1998–2017

Fig 15

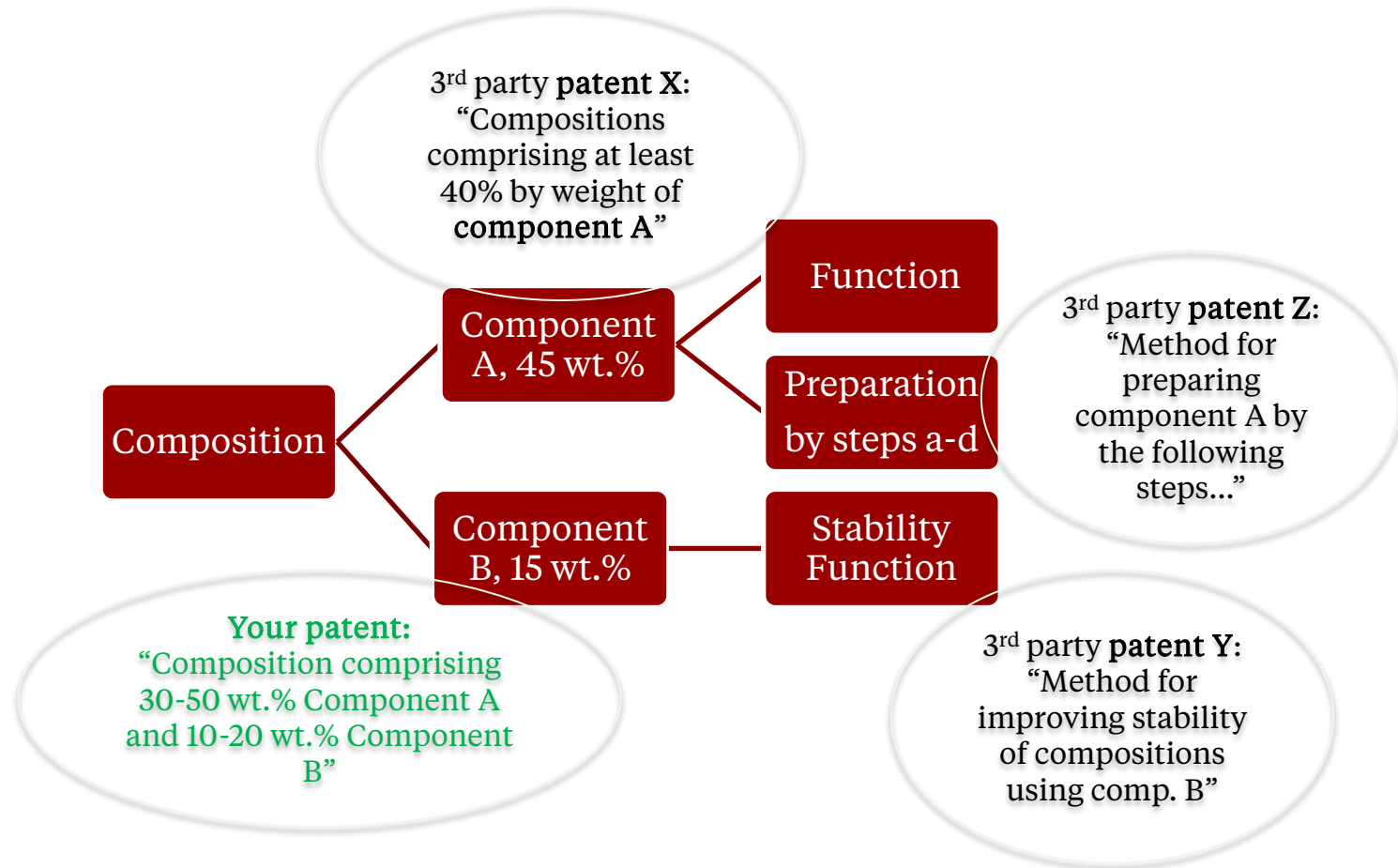
Biotech/Pharma surpassed Medical Devices in this year's study as the industry with the highest median damages award.



The number of identified decisions is indicated within the respective row.

Once I have a patent, I can use my invention any way I want, right?

NO!
Having a patent \neq Freedom to operate



Just a bump
or
an actual barrier?



Hblad.no



Istockphoto.com



How: Study third party IP!

- Define product/process/use; **Identify key elements** and “sub-components” or related aspects of technology
- Business plan/model; where to produce, where to sell
- Search for/in patent literature - Restrict scope of search - Use alternative keywords, search terms
- Thorough analysis of potentially relevant patents
- Compare overlap of technology elements with patent claim scope
- Opinion



Type of searches:

Novelty searches (patents or trademarks)

State of the art searches/landscaping

Know your competitors: surveillance

Freedom to operate (FTO)/Clearance;

Validity searches; Are the identified patents valid?

Patent infringement searches

Sources:

Non-patent literature:

Scifinder, PubMed, Google, Youtube, books, articles, posters, news papers....

Patent Sources:

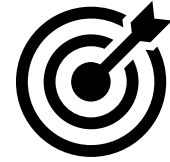
Commercial databases:

Patbase (Minesoft), Derwent World Patent Index (Thomson Innovation), PatSeer

Free databases: Espacenet, USPTO, Patentscope (WIPO), NIPO (Patentstyret), Google patent search



Analysis of third party patents



- Not all patent applications are granted \Rightarrow If relevant pending applications – put on surveillance?
- Patent protection is territorial \Rightarrow Free to use technology in non-patented territories
- Patents have a limited duration \Rightarrow Max. 20 year, some are abandoned before max. patent term – check!
- Patents have a limited scope \Rightarrow Analysis of patent claims; Compare elements of technology with elements in patent claims

Analysis of 3rd party patents

3rd party patent X: “at least 40% by weight of component A”

EP patent: validated in GB and DE only

US: “at least 40 % A, and at least 10% of component C”

Composition

Component A, 45 wt.%

Function

Preparation by steps a-d

Component B, 15 wt.%

Stability Function

3rd party patent Z: “Method for preparing component A by the following steps...”
Filed August 2001

3rd party patent Y: “Method for improving stability of compositions using comp. B”
Filed Nov. 2019 – pending

Your patent: “Composition comprising 30-50 wt.% Component A and 10-20 wt.% Component B”



When to do an FTO analysis

When to do an FTO analysis

Phase of project	3 rd party IP
Feasibility phase (early research)	Landscape searches; identify key competitors and potential obstacles
Research (pre-clinical)	Identify any third party patents relevant to lead/backup candidate and formulate a mitigation plan; Preliminary FTO analysis?
Development phase (clinical phase)	Act on mitigation plan if necessary; update/do FTO analysis, perform validity assessments, seek licenses?
Product approval (commercialization)	Put any licenses in place, set up patent watch, seek invalidation of barrier patents?

FTO analysis before major milestones/costs. Revisit/update!

How to obtain FTO?

Legal and/or IP management strategies

License/cross-license

Oppose



R&D strategies

Modify



Business strategies

Ignore the problem

M&A

Adjust market scope

Abandon





18. MAI 2021

Legal and/or IP management strategies

License: Authorization from patent holder to use patented technology for specified acts, in specified markets, for specified time. Terms/conditions!

«Remove» barrier patent; Oppose/invalidate -Seek to remove barriers, and/or as means for negotiations

R&D strategies

Change your technology (product, process, use) to be outside third party patent claims

- **Better sooner than later**
- **May be minor adjustment needed?**





Business strategies

Ignore problem – risky!

May be summoned to court, infringement/litigation

Seek partnership with patent holder; Merge or acquire

Select «free» markets (no third party barrier patent)

Abandon project

Cases;

Famous licenses

Norwegian court cases

Famous patents licensed or litigated

- Amazon; Patent on «1-click» buying (US5,960,411). Licensed to at least Apple.
- FAANG cross-licenses (Facebook, Amazon, Apple, Netflix and Google).

Biotech, US:

- Cohen-Boyer patents: Splicing genes making recombinant proteins (US4,237,224). Licensed broadly, > \$200 million.
- Lilly/Genentech patents: Use of the cDNA encoding human growth hormone (US4,363,877). Extensive litigations.
- Axel Patents (Columbia Univ.) Directed to co-transformation - a foundational method of biotechnology; licensed patents nonexclusively and broadly, > \$790 million.

Norwegian infringement cases



- LB-2003-9824 ScanPharm-Generics/AstraZeneca.

Patent **NO 174239** Dosing form of Omeprazol (AstraZeneca).

Validity of patent? **Yes!**

Infringement? **Yes!** ScanPharm to pay about 4.5 mNOK in case costs for invalidity and infringement to AstraZeneca.

- LB-2003-9305 AstraZeneca/Ratiopharm AS

Patent **NO 174239**. Infringed by Ratiopharm's omeprazole product? **No!** Appeal, long process.

AstraZeneca to pay Ratiopharm's case costs of 3.8 mNOK + costs of expert lay judges.



NORGE

(12) **UTLEGNINGSSKRIFT**

(19) NO

(11) **174239**

(13) B

(51) Int Cl⁵ A 61 K 31/44

Styret for det industrielle rettsvern

(21) Søknadsnr	871790	(86) Int. inng. dag og søknadsnummer	
(22) Inng. dag	29.04.87	(85) Videreføringssdag	
(24) Løpedag	29.04.87	(30) Prioritet	30.04.86, GB, 8610572
(41) Alm. tilgj.	02.11.87		
(44) Utlegningsdato	27.12.93		

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Satoshi Morigaki, Taka-gun, Hyogo, JP
Minoru Oda, Nakatsu-shi, Ohita, JP
Naohiro Ohishi, Chikugo-gun, Fukuoka, JP
(74) Fullmektig Oslo Patentkontor AS, Oslo

(54) Benevnelse **Fremgangsmåte for fremstilling av et oralt, farmasøytisk preparat**

(56) Anførte publikasjoner Ingen

(57) Sammendrag

Farmasøytisk preparat inneholdende omeprazol sammen med en alkalisk reagerende forbindelse eller et alkalisalt av omeprazol eventuelt sammen med en alkalisk forbindelse som kjernemateriale, en eller flere underbelegningssjikt omfattende inert reagerende forbindelser som oppløselige eller raskt desintegrerende i vann, eller polymere, vannoppløselige, filmdannende forbindelser, eventuelt inneholdende pH-bufrende, alkaliske forbindelser og et enterisk belegg så vel som en fremgangsmåte for fremstilling derav, og anvendelse ved behandling av gastrointestinale sykdommer.

Krav 1:

1. Fremgangsmåte ved fremstilling av et oralt, farmasøytisk preparat som er stabilt mot misfarging og som inneholder omeprazol som den aktive bestanddel, karakterisert ved at kjerner inneholdende omeprazol blandet med en alkalisk reagerende forbindelse, eller et alkalisalt av omeprazol, eventuelt sammen med en alkalisk reagerende forbindelse, belegges med ett eller flere inert reagerende underbelegningssjikt omfattende tablettbindemidler som er oppløselige eller raskt desintegrerende i vann eller polymere, vannoppløselige, filmdannende forbindelser, eventuelt inneholdende pH-bufrende, alkaliske forbindelser, mellom den alkalisk reagerende kjerne og et yttersjikt som er et enterisk belegningssjikt, hvoretter de underbelagte kjernene ytterligere belegges med nevnte ytre enteriske belegningssjikt.



NORGES HØYESTERETT

Den 22. desember 2009 avsa Høyesterett dom i

HR-2009-02402-A, (sak nr. 2009/694), sivil sak, anke over dom,

Torbjørn Kvasshem (advokat Amund Brede Svendsen – til prøve)

mot

Stiftelsen SINTEF (advokat Gunnar Meyer)

STEMMEGIVNING :

- (1) Kst. dommer **Sverdrup**: Saken gjelder spørsmålet om en forskningsstiftelse har begått middelbart patentingrep ved overlevering av et dataprogram til oppdragsgiveren i et forskningsprosjekt, jf. patentloven § 3 annet ledd.
- (2) Torbjørn Kvasshem ble meddelt et patent 22. januar 1992. Patentet omfattet fremgangsmåte for telling av enkeltgjenstander/individer, eksempelvis levende fisk, og et telleapparat egnet for gjennomføring av fremgangsmåten. Gjennom sitt enkeltpersonsforetak AquaScan Siv.ing. Torbjørn Kvasshem startet Kvasshem i 1990 produksjon av en fisketeller på grunnlag av oppfinnelsen. Produksjonen tok særlig sikte på salg til fiskeoppdrettsnæringen. Fisketellingen var basert på en optisk registrering av fiskens areal, ikke telling av enkeltfisk.
- (3) Én av kjøperne til produktet var Brødrene Wingan AS (Wingan), som primært drev med vaksinasjon av fisk og utvikling av innretninger for å foreta vaksineringsen. I 1994/95 ble det etablert et kommersielt samarbeid mellom Wingan og Kvasshem, der Wingan kjøpte flere fisketellere av Kvasshem.
- (4) Wingan kontaktet i 1998/99 Stiftelsen SINTEF, som er en uavhengig forskningsinstitusjon som i første rekke driver oppdragsforskning. SINTEF fikk i 1999 i oppdrag av Wingan å yte bistand til utvikling av en ny type fisketeller som skulle sikre en mest mulig nøyaktig beregning av antall fisk og av biomasse (vekt) på fisken. Ifølge prosjektets reviderte målsetning skulle SINTEF utvikle måleutstyr i form av en fisketeller

Example of indirect infringement

Case 2009/694 Sintef/Kvasshem

-Sintef developed equipment and computer program for counting of fish, for Wingan

-Sintef enabled Wingan to use invention patented by Kvasshem (patent no. 168151)

-Indirect infringement of Kvasshem's patent

-No "research exemption"

-Not to use patented technology for economical utilization.



Conclusions

FTO – ensure that you can operate without infringing others' rights; reduce risks

Aim to patent your technology - but it does not necessarily give you FTO

Be proactive – know your competitors and their IP - read patents

Survey key patent applications/competitors

Conduct FTO analyses before major milestones or costly operations

Revisit and update the analyses

Have a strategy for how to obtain FTO (legal/R&D/Business)

To be continued...



Del 4

26. mai 2021, kl. 14.00-15.00

Er bedriften sikret med gode kommersialiseringsavtaler?

Håkon Tysnes Kaasin, advokat