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# LEGAL AND REGULATORY ASPECTS OF IPR

health
food
technology

LifeScience@Work
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# Content

- Short recap of IPR
- Infringement / Exempted use
- Ownership / Bankruptcy
- Additional / other forms of protection
  - SPC
  - Orphan Drug Act
  - Data exclusivity

# Intellectual Property

| Innovation | Protection of names, design | Other |
|---|---|---|
| Patents 20 years* | Tradename | Copyright* |
| Plant variety rights | Trademark* 5 years (unlimited extensions) | Database rights*** |
| Semiconductors topography rights | Design rights* 5 years (4X extension) | Know how / trade secrets |
| | (domain names) | |

* *Limited in time, scope and territory. Can sometimes be extended with SPC*

*** Stand alone software can not be patented in Europe unless integrated in hardware. Patenting in US is (still) possible if it is an "inventive concept" (not purely functional)*

**** cave: General Data Protection Regulation 2016/679*

# Patent requirements

## Substantive requirements

- **Novelty**
  - Invention should not be part of state of the art *anywhere* in world
- **Inventive step**
  - Invention should not be obvious for person skilled in the art
- **Industrial applicability**
- **Patentable subject matter**
  - (a.o. Myriad, Prometheus, Brustle)

# Infringement

- **commercial use**
  - manufacture, sale, import, export, distribution or offer to do so
  - If you have a patent you may not have FTO (!)

- **Counter actions**:

- challenge the patent
    - Opposition (9 months from grant US or European patent)
    - Invalidity actions (country by country)

    - Wait until patent expires and use research exemption

    - Move to countries without patent protection

    - Negotiate a license

# Exempted Use

- **Research Exemption**
  - Experimental use privilege
  - Regulatory approval privilege (Bolar)
- **Prior use**
- **Plant Variety Rights**
- **Monsanto Case** (Eur. Court of Justice July 6, 2010

  Article 9 Biotech Directive: Patent protection extends to all material in which the product in incorporated and in which the genetic information is contained and performs its function

# Research Exemption

| Countries | Research Exemption | Research Tools |
|---|---|---|
| The Netherlands | -Experimental use DPA 53(3) & case-law (second medical use):<br>- Regulatory Approval 53(4) | No |
| U.S.A. | -Bolar-type exemption,<br>-Reasonably related,<br>-Lead to FDA approval; | Yes,<br>depends |
| France | -Experimental use;<br>-Regulatory Approval – very broad; | unclear |
| Germany | - Clinical Trials I;<br>- Clinical Trials II; | Yes, if leads to a dependent patent |
| UK | -Experimental use- adopted Clinical Trials I in a restricted way;<br>-Considerations to include innovative drugs under Research exemption. | No |
| Belgium | -BPA 28(1)(b): “scientific purposes on and/ or with”;<br>-BAMP 6bis(1)(12): generic drugs. | Yes |

# KNOW HOW LICENSE I

- EU Directive 2016/943 on undisclosed know how and business information (“trade secrets”)

- Trade secret is
  - (a) not publicly available within the relevant target group,
  - (b) has value because of its secrecy; and
  - (c) is subject to reasonable confidentiality measures

- Member states must take measures to ensure that illegal use of trade secrets can be prosecuted

- Directive entered into force on July 5, 2016. 2 years implementation time

# KNOW HOW LICENSE II

- Either stand alone or in combination with patents to enable the licensee to use the inventions in the patent rights

- No maximum duration to know how license (for as long as know how is know how)

- Royalties on know how can exceed the patent life and/or be asked in countries without patents

# EU Competition rules

- Regulation 316/2014 on technology transfer agreements
- Based on “competitors” and “market share” mechanisms
- “Black clauses”
  - Article 4
    - Price binding and others
  - Article 5
    - Exclusive grant back / assignment of improvements
    - Non-challenge clause (save for termination in such event in exclusive license)
    - Restriction on licensee’s ability to exploit its own technology unless (i) competitors or (ii) necessary to prevent disclosure of know how

# Ownership of IPR

- Ownership of IPR
  - creation/invention
  - by law (employee / employer / “work for hire”)
  - Assignment (by deed)
  - inheritance;
- Legal framework governing Joint IP Ownership: national law
- All countries: “an agreement to the contrary” prevails over national law default

# The Rights of Joint Patent Owners

| Countries | to Use individually | to Assign individually | to License individually | Considerations |
|---|---|---|---|---|
| The Netherlands | Yes | Yes | No | - non-exclusive (N-E) and exclusive (E) licensing with common consent |
| U.S.A. | Yes | Yes | Yes | -N-E. licensing individually;<br>-E. licensing with common consent' |
| France | Yes | Yes, but preemptive rights co-owner | Yes | -N-E. licensing individually,<br>-equitable compensation – amicable agreement – F.I.C.<br>-E. licensing with common consent or Court authorization; |
| Germany | Yes | Yes | No | - Common consent for N-E. and E. licensing; |
| UK | Yes | No | No | - deadlock situation, Comptroller intervention; |
| Belgium | Yes | Yes | No | - N-E. and E. licensing with common consent;<br>Court authorization. |

# Bankruptcy of Patent Licensor

| Countries | Consequences |
|---|---|
| The Netherlands | Trustee must respect license if no burden on the bankrupt estate |
| U.S.A. | Option licensee to retain license |
| France | Discretion trustee |
| Germany | Discretion trustee<br>New licensee protection law put on hold |
| UK | Trustee may disclaim onerous property (a.o. any unprofitable contract or unsellable / unreadily sellable property)<br>But: right of licensee to apply for ownership<br>Unclear whether licensee remains entitled to exercise rights |
| Belgium | Discretion trustee |

# Recent European Case law

- **Berzona** (Dutch SC 11/7/2014)
  - Trustee must respect rights licensee if no burden on bankruptcy estate

- **Oracle / Usedsoft** (EcJ 3/7/2012)

  - License for unlimited time at one time payment is considered equal to purchase:
    - Right of IP holder is “exhausted” with regard to such copy: IP holder deemed to have received reasonable price;
    - Also applicable for downloaded software (but not for SAAS / cloud: software as a service)

# US case law

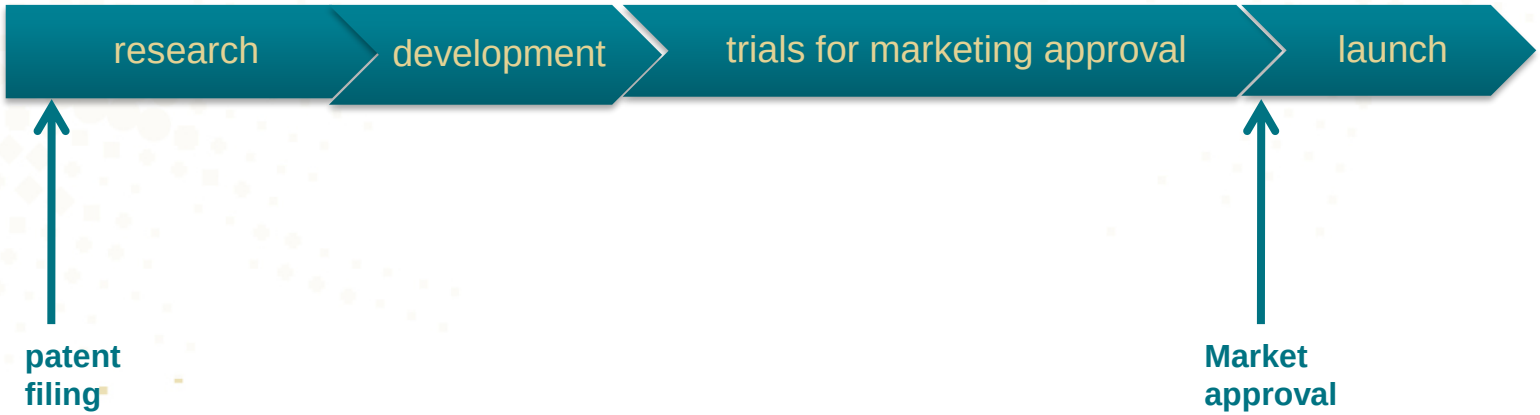
- **Sunbeam Products, Inc. v. Chicago American Manufacturing**, LLC, (Federal Circuit, 9/7/2012)
    - Rejection of license is merely constituting a **breach**. Outside bankruptcy, rights licensee would continue. So also within bankruptcy. Bankrupt licensor does no longer need to perform. But licensee's rights are unaffected. Also for trademarks
- **Jaffe v. Samsung Electronics** (US Federal Circuit, 3/12/2013)
    - Bankruptcy Qimonda AG (Germany)
    - US licensees of European licensor were granted protection under 365(n) US Bankruptcy Code

# Other forms of protection

- Supplementary Protection Certificates
- Orphan Drug Designation
- Data Exclusivity

# Supplementary Protection Certificate

- Stand alone right which extends (a part of) the patent protection
- To compensate for time during which the invention could not be marketed because of the obligation to (first) prove the safety and efficacy of such products;



# Supplementary Protection Certificate

- Period between **(i) patent application and (ii) grant of marketing authorisation** minus 5 years

**NB:**
- maximum 5 years after patent expiry
- maximum 15 years after grant first MA

Example:

| | |
|---|---|
| • patent application | 1/1/1989 (exp 1/1/2009) |
| • authorization granted | 1/1/2002 |
| • lapsed period: | 13 years, |
| • minus 5 (prescribed in art. 13) | 8 years |
| • but still only 5 years (prescribed in art. 13); | until 1/1/2014. |

# Supplementary Protection Certificate

- Only for **medicinal** products and **plant protection** products
    - **But**: case law in Germany and The Netherlands: also for integral device-drug combinations (approved under MDD or MDD implantable device Directive) if active ingredient is ancillary to medical device and would, as stand alone, fall under MP Directive
    - EcJ: no decision yet. But tendency to be favourable to analogue application when similar rigorous safety / efficacy requirements

# Orphan Drug Exclusivity

| Europe | US |
| --- | --- |
| Affecting <5: 10,000 in Europe at time of designation (<253,000) | Affecting <200,000 in US at time of designation |
| Only granted when (i) no current diagnosis / treatment / prevention or (ii) applied product offers significant benefit to patients | Same |
| If granted: 10 years market exclusivity plus fee reduction plus advice on clinical trials<br>+ 2 years extension when PIP executed | If granted: 7 years market exclusivity plus fee reductions plus advice on clinical trials |

# Data Exclusivity

- Directive 2001/83/EC (as amended in 2004)
- EU encourages **generics (**reduce costs of healthcare**)**
- To avoid unnecessary (repeated) animal and human studies, generic owner can ask authorities to asses safety and efficacy on basis of similar product already on the market (“reference product”)
- **But:** originator obtains data exclusivity time:
  - 10 years from grant marketing authorisation (MA) (‘8+2’; for 8 years others cannot apply for MA, and for another 2 years the medicinal product cannot be marketed.)
  - 10 years for medicinal products approved centrally

# IE-contracten: CDA / NDA

**2 benamingen voor hetzelfde contract**
•Confidentiality disclosure agreement
•Non-disclosure agreement

**Essentie**
•Creëren juridisch kader voor uitwisseling van vertrouwelijke informatie met het oog op verdere samenwerking

**DO's en DON'Ts**
•Start geen gesprek voordat CDA is ondertekend
•Beschouw zo'n verzoek niet als bureaucratisch of gebrek aan vertrouwen
•Beschrijf duidelijk: wat?(bepaalde info), waarom? (soort samenwerking) en waarvoor? (zg. field)

# IE-contracten: MTA

**Essentie Material Transfer Agreement**

•Scheppen van juridisch kader voor uitwisseling van materialen voor testen van bepaalde materialen, bv. cellijnen

**DO's en DON'Ts**

•Stuur geen materialen op (en ontvang ze ook niet) voordat MTA is ondertekend ➔ voorkom "besmette koelkast"
•Definieer zorgvuldig toegangsrechten tot resultaten ➔ voorkom blokkades eigen onderzoek
•Maak vooraf inschatting: is follow-up (contracten) aannemelijk?

# IE-contracten: Collaborative Research Agreement

**Essentie**

•Partijen ondernemen gezamenlijk onderzoek
•Afspraken over financiering en eigendom & exploitatie resultaten

**DO's en DON'Ts**

•Start met onderzoeksplan en budget, contract volgt daarna
•Maak inschatting van verwachte uitkomst ➔ bescherming noodzakelijk?
•Indien bescherming ➔ wie betaalt daarvoor?
•NB Sponsor onderzoek krijgt niet automatisch alle rechten, want "*ownership follows inventorship*"
•Overweeg overdrachtsoptie voor geval partij interesse verliest in beschermde uitvinding

# IE-contracten: License Agreement

**Essentie:**

•Toegang tot technologie tegen betaling van vergoeding

**DO's en DON'Ts**

•Definieer duidelijk "licensed rights"
•Neem een specifiek "territory" en "field" op
•Overweeg een zg. "research exceptie"
•Zorg voor "return on investment" (RoI) d.m.v. (i) upfront payments, (ii) royalties, (iii) milestones (iv) verslaglegging en rapportages
•Zijn garanties/vrijwaringen noodzakelijk?

# IE-contracten: Services or Consultancy Agreement

**Essentie:**

•Verschaffen van advies/verrichten van diensten als “aangenomen werk”

**DO’s en DON’Ts**

•Definieer duidelijk het aangenomen werk
•Specificeer uurtarieven of zg. “*fixed fee*”
•Realiseer dat IE-rechten doorgaans eigendom zijn van opdrachtgever
•Tref echter een regeling voor toevalstreffers (“*serendipity findings*”)
•Overweeg of dit type contract op juiste wijze relatie partijen reflecteert

# Spin-off bedrijven

**Exploitatie strategie afhankelijk van soort bedrijf**

•Dienstverlening centraal (“*service company*”)
“I can do what you can, but better/cheaper/faster”

•Technologie centraal (“*technology company*”)
**“**I have a technology, so I can (others let do) do what nobody else can”

•Product centraal (“product company”)
“I have a product that nobody else can provide”

# Zooming in: service company

**Voorbeeld service company:**
•Contract Research Organization (CRO)

**Vereisten**
•Grote mate van expertise op specifiek gebied
•Geheimhouding

**IE regime**
•Eerder trade secrets en know-how dan octrooien

**Deliverables**
•Klant ontvangt eindproduct – geen inzicht in toegepaste procedures

# Zooming in: technology company

**Voorbeeld technology company:**
•Meeste biotech start-ups, bv. Octoplus ➔gebruikt zg. "*drug delivery technology*" om "*controlled release*" producten voor klanten te ontwikkelen

**Vereisten / IE regime**
•Specifieke know-how en octrooien
•Geheimhouding

**Deliverables**
•Klant ontvangt eindproduct + dossier; moet inzage in toegepaste procedures kunnen hebben
•Niet zelden ontwikkelt technology company tot service company of verhandelt het in later stadium eigen product

# Zooming in: product company

**Voorbeeld product company:**
•Prosensa (ontwikkelt geneesmiddel voor Duchenne Muscular Distrophy) of Philips (richt zich meer en meer op life sciences sector met specifieke producten)

**Vereisten**
•VC Investeringen voor vervolgproduct (“one trick pony” volstaat niet)

**IE regime**
•Minimum aan exclusiviteit (octrooien, auteursrecht, modellen) om tijdelijk monopolie te garanderen

**Deliverables**
•Klant ontvangt eindproduct – geen inzicht in toegepaste procedures

# Algemene principes (1)

“**Begin with the end in mind**”

•Wat voor product wil ik maken? Bv. geneesmiddel of medisch hulpmiddel?
➔ type product bepaalt toepasselijke regelgeving

•Op welke markten wil ik actief zijn?

•Wat is mijn business model?

•Heb ik zelf alle expertise in huis?  Zo nee ➔ met wie moet ik samenwerken om mijn doel te bereiken?

•Kan ik mijn product beschermen met IE-rechten of loop ik tegen IE-rechten van derden aan?

# Algemene principes (2)

**Omgaan met commerciële risico's**

•Onderhandel altijd: standaard voorwaarden bestaan niet

•Als je het zelf niet snapt (of de ander het niet uit kan leggen) is er een risico ➔ huur specialisten voor voor specifieke (juridische) zaken

•Wanneer de wederpartij het contract heeft geschreven, heeft hij er beter over kunnen nadenken dan jij ➔ gezamenlijk opstellen Term Sheet

•Zijn er nog algemene voorwaarden van toepassing ➔ zo ja: wat staat erin?

# Contracten in de value chain

Denk aan de volgende contracten om  een life sciences product in de markt te zetten:

- Contracten met werknemers en consultants
- Contracten met leveranciers, distributeurs, fabrikanten en klanten
- Financieringscontracten
- Licenties

# Term Sheet algemeen

**Overeenstemming op hoofdlijnen**

•Regelt essentialia overeenkomst➔ verschilt per overeenkomst, maar doorgaans:

- Soort contract
- Duur
- Vergoeding
- Beëindiging etc.

Soms gaat hieraan aan vooraf:

•Letter of Intent
•Memorandum of Understanding

# Term Sheet Licentieovereenkomst

**Licentienemer**: van wie heb ik waarvoor licentie nodig?

**Licentiegever**: wat is de reikwijdte van te verstrekken rechten?
•Inhoud licentie: welk stuk IP?
•(non) exclusief?
•Sub-licenties?
•Territorium?
•Field?

**En verder**:
•Hoe creëer ik incentive voor licentienemer met technologie aan de slag te gaan? zg. “*anti-shelving clause*”
•Beëindiging (Change of Control, wanprestatie, faillissement)
•(Overdrachts)opties?

**Term Sheet between [*name parties*]**
**re. [*name technology*]**

| | |
|---|---|
| Joint purpose of the parties | Production and sales of apparatus xxx |
| Nature of contract | Exclusive license and collaboration agreement, preceded by 3 months exclusive option period |
| Object of contract | Intellectual Property and know-how vested in the xxx technology, including any Improvements |
| Field | Radiology |
| Territory | Worldwide |
| Term of contract | Linked to validity of the Patents |
| Intellectual Property (IP) | Patents (granted, pending and yet to be filed), trademarks and designs |
| Ownership IP + Improvements | *Name party A* |
| Maintenance costs IP + Improvements | *Name party A*<br>maintenance costs re specific improvements for *party B* |
| Milestones | • Upon execution option agreement: € 100 K (*estimated date*:……)<br>• Upon execution of license and collaboration agreement: € xxx K (*estimated date*:……)<br>Milestones remain due and payable if termination by *Party B* for convenience |
| Collaboration | Party A shall provide Party B support, at an hourly rate basis, for: [*describe specific tasks*]<br>Estimated costs: € 25 K per calendar quarter |
| Royalties | • € 500 per unit produced by or on behalf of *Party B* with yearly minimum of € 50 K (*estimated start date:* …..) |
| Termination clauses | • By both parties in case of breach of contract, suspension of payments or bankruptcy<br>• By *Party B* taking into account a reasonable notice period<br>• By *Party A* in case *Party B* does not make full use of licensed technology ("anti-shelving" clause) within specified period<br>*NB it may well be that Party A will attract minority investors in order to fortify its company structure. This should not be a ground for termination of the contract.* |
| Confidentiality | Should be ensured re. Confidential Information both during and after validity License Agreement |
| Applicable law | Dutch law |
| Dispute resolution | ICC arbitration |

# Casus 3DVUMC

**Feiten**

- *LaserLaB* van VU en *Radiologie en Nucleaire Geneeskunde* van VUmc hebben gezamenlijk *proof of concept* ontwikkeld voor een apparaat voor beeldvorming (MRI scanner) en 3D printing.
- Apparaat kan o.m. worden gebruikt voor vervaardigen van protheses.
- Voor dit apparaat is octrooibescherming aangevraagd.
- Verdere ontwikkeling van dit apparaat binnen VU en/of VUmc ligt niet voor de hand.
- Daartoe wordt een spin-out opgericht: **3DVUMC**.

**Vragen**

- Wat is de beste *way to market* voor deze MRI scanner/3D printer?
- Welke controle behouden VU en Vmc, welke rechten krijgt 3DVUMC?

# Term Sheet between VU, VUmc and 3DVUMC re. MRI scanner/3D printer

| | |
|---|---|
| **Licensors** | VU and VUmc |
| **Licensee** | 3DVUMC |
| **Nature of contract** | |
| **Object of contract** | |
| **Field** | |
| **Territory** | |
| **Term of contract** | |
| **Ownership IP + Improvements** | |
| **Maintenance costs IP + Improvements** | |
| **Milestones** | |
| **Royalties** | |
| **Assignment option** | |
| **Termination clauses** | |
| **Confidentiality** | |
| **Applicable law** | Dutch law |
| **Dispute resolution** | Competent Court in Amsterdam |

# Conclusies

**Belangen van partijen lopen niet altijd parallel**

- Perspectief licentiegever: maximum potentieel *Licensed IP* realiseren
- Perspectief licentienemer: zo groot mogelijke vrijheid voor exploitatie *Licensed IP* tegen zo laag mogelijke kosten

**Gemeenschappelijke deler**

- indien geen *deal*, dan vaart niemand wel
- Indien wel *deal*, dan profiteren beide partijen

**Vereisten voor deal**

- Kennis van technologie en marktpotentieel
- Inzicht in concurrentie
- Wederzijds vertrouwen en respect

# THANK YOU

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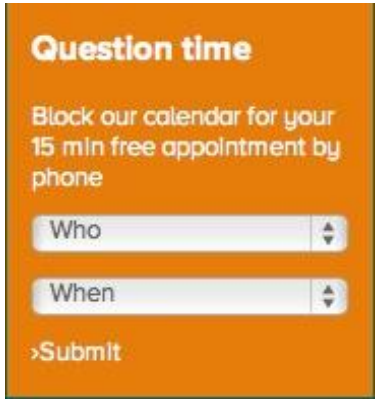


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