

Socially Responsible Licensing

Approach in the Netherlands

Mrs C.J.M. Coch, LLM

CEO a.i. Brightlands Maastricht Health Campus

Knowledge crossing borders

Background and core objective:

- High prices of medicines
- Publicly financed research may not lead to extremely high cost of care and other socially undesirable developments
- 2018 Minister of Medical Care and Sport invited the NFU to develop its views on tech transfer and its role

What seems to be the problem?

The Covid-19 pandemic (re)fueled the public debate about the accessibility of health patents



Socially Responsible Licensing

Developing the tools so people take action



Aim

Translate research results swiftly into **medical innovations** that benefit society and public health (valorisation)

Licences

Requires granting **licenses** for using inventions or know how to commercial partners (start ups or existing companies)

Trade off

Making money versus **affordability** and **availability**

Mission

Ensure that medical innovations (including medicines) will be **reasonable priced** and **broadly available**

Tool

10 Principles, a **Toolkit** and a **License Negotiation Model**

Dutch University Medical Centre are taking their responsibilities

2019: 10 principles for Socially Responsible Licensing

2020: Patent License Toolkit

2022: Licensing Negotiation Model

Socially Responsible Licensing
Toolkit for knowledge institutions
for a smooth and rapid conversion of academic knowledge into valuable products and services

10 Ten principles

- The development and sharing of knowledge and making that knowledge useful for society are the core tasks of the knowledge institutions. Sometimes they can do this themselves, sometimes they collaborate to achieve this.
- For collaboration with, for example, startups or other companies, knowledge institutions prepare contracts (licences).
- The development of the 10 principles was initiated to inform the Minister of Public Health, Welfare and Sport regarding the possibilities for socially responsible licensing.

Get to know the 10 principles
Please turn over →

Implementation & Evaluation

Implementation:

- Reporting application of the 10 principles and the use of the SRL-toolkit (or similar stipulations) through the annual reports of the knowledge institutions.

Evaluation:

- The SRL-toolkit is actively managed by the knowledge institutions.
- Experience in use and development of societal debate as basis for improvement and possible expansion.

Goal: sound definitions

Next phase is defining 10 principles.

- Developing a collection of contract specifications that knowledge institutions can use for agreements with companies.
- Agreements about the use of patented knowledge for different sectors.
- Stipulations that knowledge institutions use for negotiation about the licence contract.
- Parties negotiate about articles. The parties are free to deviate or supplement as the situation requires.
- A 'toolkit' offers possibilities that take the situation into account.

For the 10 principles, the SRL-toolkit and more information, also consult
www.nfu.nl/english/research-and-innovation

Development of SRL-toolkit

The workgroup members are primarily responsible for preparing the contents of the SRL-toolkit. They are involved with this in the daily practice and will work with the SRL-toolkit in the future.

Who was represented?

- Representation from KTO-group, consisting of KnowledgeTransferOfficers/KTO-directors
- Investors
- Entrepreneurs

The **sounding board** group members gave their view and opinion of the process and the SRL-toolkit. They often have an indirect interest.

Who was represented?

- Public and charitable research financiers
- Political and societal organisations
- Umbrella organisations from the business community

Impact analysis

During the development of the SRL-toolkit, an impact analysis was done. What's the potential impact of the use of the SRL-toolkit by Dutch knowledge institutions? Opportunities for streamlining negotiations and threats to the innovation climate were mentioned, among others. All the specified considerations concern expectations – there are not yet any concrete experiences with the SRL-toolkit. These experiences will start accumulating now.

Ten principles of SRL

- Academic institutions strive to ensure that research contributes to societal and/or economic development.
- Academic institutions retain the right to continue using their own results and to let them be used for research and education.
- Academic institutions make licensing agreements exclusively with parties that can reasonably be expected to continue developing the knowledge and are committed to doing so.
- Academic institutions verify that partners with whom they have arranged a licensing agreement do not have societal objectives that are in conflict with their own.
- Academic institutions ensure that no traditional or indigenous knowledge or inventions based on it are included under intellectual property rights without appropriate agreements being made with the rights holders.
- Academic institutions, when applying these principles, take those parties that are directly concerned into account and ensure that they are adequately informed of the wishes and interests of those interested parties.
- Protection and licensors must not conflict with the legal task and societal mandate of academic institutions.
- Licences stimulate the development and use of technology and knowledge and bestow rights that are clearly defined and limited. Consideration must be given to both the commercial interests of the current partner and any other future applications. Plus unintentionally including future results or the results of others must be avoided.
- In certain countries, licences provide space to encourage or ensure marketing access or development, where possible. They can also offer possibilities to encourage or ensure application in certain sectors.
- Licences ensure that the price-setting of the final products and/or services does not endanger accessibility.

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The Hague / Utrecht, August 2020

The 10 principles

1-5

1

Research for Societal Benefit

Ensure research aims for societal or economic impact, given public funding

2

Continued Use and Openness

Retain the right to use research for further research and education

3

Responsible Licensing Partners

Partner only with entities able and committed to further developing the knowledge

4

Alignment of Societal Objectives

Ensure licensing partners' goals align with institutional values

5

Respect for Traditional or Indigenous Knowledge

Include traditional or indigenous knowledge only with proper agreements

The 10 principles

6-10

6

Inclusion of Stakeholder Interests

Consider and inform all stakeholders when licensing

7

No Conflict with Societal Mandate

Licensing must not conflict with legal task and societal mandate of academic institutions

8

Well-Defined Licenses

Licenses should clearly define rights, balancing current commercial interests while allowing for future research and applications, without unintentionally including others' work

9

Flexibility for Market Access

Design licenses to encourage market access and social benefits

10

Accessible Pricing

Include provisions to keep end products or services affordably priced to maximize accessibility

The hardest one to enforce: Accessibility vs. Innovation

Misalignment of Interests between academic institutions and commercial partners



The 10th principle may act as a disincentive for businesses who invest heavily in bringing an academic innovation to market

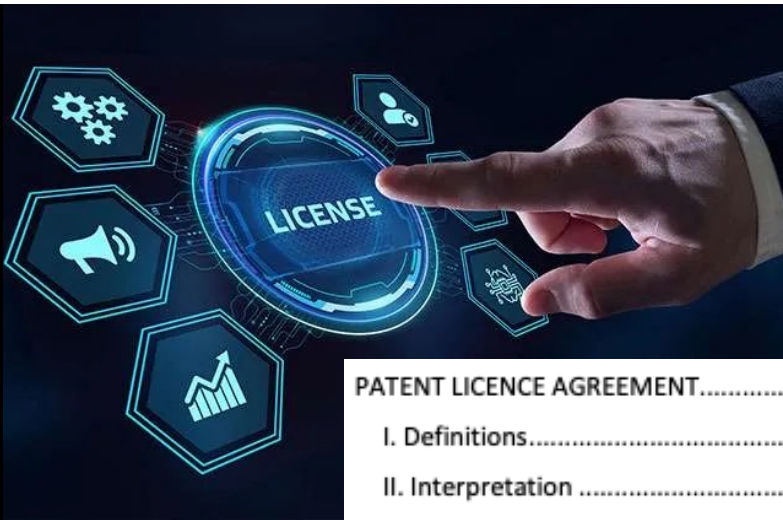
The 10 Principles

Creation:

- Drafted by a sizeable group of (mostly public) stakeholders.
- Subsequently opportunity for comments by 'interested parties' (i.e. private parties).
- Final version open for public consultation.

Duration: approx. 18 months

- PRO's
 - All (public) perspectives covered
 - Firm basis in policy and relevant public frameworks
- CON's
 - Many opinionated participants with limited 'technical know-how'
 - Absence of commercial perspective during drafting impacting acceptance and understanding



The Toolkit

Boiler plate patent license agreement & optional clauses

PATENT LICENCE AGREEMENT.....
I. Definitions.....
II. Interpretation
III. Grant of Rights
IV. Sublicence.....
VII. Financial Compensation & Payments ..
VIII. Anti-shelving & Diligence.....
IX. Reports, records & Audit
X. Prosecution & Maintenance
XI. Enforcement & Litigation.....
XIII. Confidentiality & Publications
XIV. Liability & Indemnity.....
XV. Representations & Warranties
XVI. Term & Termination
XVII. Miscellaneous.....
XVIII. Law & Forum
Annexes

CLAUSE LIST AND EXPLANATORY NOTES
I. Definitions.....
II. Interpretation
III. Grant of Rights
IV. Sublicence.....
V. Material
VI. Support Services
VII. Financial Compensation & Payments
VIII. Anti-shelving & Diligence.....
<i>Access for Humanitarian Purposes</i>
<i>Insurance for the benefit of end users</i>
<i>Rewarding compliance, availability, transparency</i>
<i>Ensuring active pursuing of new products</i>
<i>Genetic Resources and Traditional Knowledge</i>
IX. Reports, records & Audit
X. Prosecution & Maintenance

XI. Enforcement & Litigation.....
XII. Purchase option
XIII. Confidentiality & Publications
XIV. Liability & Indemnity.....
XV. Representations & Warranties
XVI. Term & Termination
XVII. Miscellaneous.....
XVIII. Law & Forum

Toolkit

Creation:

- Drafted by a small team of experts, based on (international) templates.
- Regular review by a large group of public and private stakeholders.
- Stakeholders collected feedback from their own group.
- Final version open for public consultation.

Duration: 12 months

- PRO's:
 - All possible stakeholders included
 - Effective drafting
- CON's:
 - Review group included many non-practitioners.
 - Too many parties with an interest in the problem instead of the solution.



Negotiation model

Creation:

- Drafted by a small team of (public and private) practitioners.
- Team members represented/liased with own group.
- Final version open for public consultation.

Duration: 12 months

- PRO's:
 - Effective drafting due to relevant expertise and interest
 - Focus on practitioner perspective
- CON's:
 - Vulnerable to the accusation of excluding (indirect) stakeholders
 - Dependent on quality of team members due to more limited review process

Review June 2023



The principles are widely applied from an intrinsic perspective



Information, negotiation model and toolkit should be easier to find.

Make them available on several websites.

Collect & communicate (best practice) experiences for monitoring, reporting and evaluation.



Improve communication and transparency on valorization in the annual reports of institutions.

Communicate more and more effective, highlighting both the valorization process (including SRL) and the outcomes/impact.



Deal with the ethical dilemmas that can be raised by SRL.

Clarify and advocate the scope and overarching purpose.

Install a body or consultation structure that can advise on ethical dilemma's.

Anchor the SRL Principles in the academic culture.

The Broader Perspective

- Broadening the scope:
 - Adopted by “Universities *of the* Netherlands”
 - Beyond Life Sciences and Health sector
 - Not just for patent licenses
- An ethical roadmap for academic institutions...
...that ensures that research outcomes benefit not just a select few, but society at large.
- Licensing agreements are not merely financial transactions...
but are social contracts as well imbued with ethical considerations and responsibilities.



Policy recommendations

From Paper to Actual Change

Implementing a Unified, Ethical Framework for Academic Licensing across the EU requires:

- Regulatory Harmonization
- Financial Support / Incentives
- Awareness and Training (communicate good practices)
- Monitoring Mechanism
- Legal Framework
- Ethical Advisory Boards
- Platforms for Stakeholder Consultations at the EU level
- Transparency





US

- focused on publicly funded research, mainly in health;
- ensures access to medicines through Global Access and public interest clauses



The Netherlands

- broader focus – health, sustainability, fairness.
- Uses the 10 Principles, the Toolkit and Negotiation Model for systematic, responsible valorization

Key differences

US approach is often sector-specific and voluntary. The approach in the Netherlands is proactive, standardized and embedded in daily practices across the knowledge transfer offices of universities, hospitals and also the industry partners

Q&A

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