ICT-2011-288048

EURECA

Enabling information re-Use by linking clinical REsearch and CAre

IP
Contract Nr: 288048

Deliverable: 7.4 Analysis of the most important IP issues within EURECA

Due date of deliverable: (31-07-2014)

Actual submission date: (31-07-2014)

Start date of Project: 01 February 2012 Duration: 42 months

Responsible WP: 7

Revision: proposed

Project co-funded by the European Commission within the Seventh Framework Programme (2007-2013)		
Dissemination level		
PU	Public	X
PP	Restricted to other programme participants (including the Commission Service	
RE	Restricted to a group specified by the consortium (including the Commission Services)	
CO	Confidential, only for members of the consortium (excluding the Commission Services)	

0 DOCUMENT INFO

0.1 Author

Author	Company	E-mail
Nikolaus Forgó	LUH	forgo@iri.uni-hannover.de
Iryna Lishchuk	LUH	lishchuk@iri.uni-hannover.de
Magdalena Góralczyk	LUH	goralczyk@iri.uni-hannover.de
Alan Dahi	LUH	dahi@iri.uni-hannover.de

0.2 Documents history

Document version #	Date	Change
V0.1	25/02/2014	Starting version, template
V0.2	15/03/2014	Definition of ToC
V0.3	01/06/2014	First complete draft
V0.4	26/06/2014	Integrated version
V0.5	11/06/2014	Updated version (send to project internal reviewers)
Sign off	14/07/2014	Signed off version (for approval to PMT members)
V1.0	31/07/2014	Approved Version to be submitted to EC

0.3 Document data

Keywords	Intellectual Property, Legal, Data, Databases, Licensing, Know-How
Editor Address data	▪ Iryna Lishchuk ▪ Partner: LUH ▪ Königsworther Platz 1, 30167 Hannover, Germany ▪ Phone: +49 511 762 8161 ▪ E-mail: lishchuk@iri.uni-hannover.de
Delivery date	

0.4 Distribution list

Date	Issue	E-mailer
14.07.2014	Pre-final	Distribution to the internal reviewers
31.07.2014	Final (1.0)	

Table of Contents

0 DOCUMENT INFO 2

0.1 Author 2
0.2 Documents history 2
0.3 Document data 2
0.4 Distribution list 2

TABLE OF CONTENTS 3
1 INTRODUCTION 6
2 DECISIONS ON INTELLECTUAL PROPERTY TAKEN TOWARDS DISSEMINATION AND EXPLOITATION 7

2.1 Decisions taken on dissemination 7
2.2 Decisions taken on exploitation 7

3 ANALYSIS OF THE MOST IMPORTANT INTELLECTUAL PROPERTY RIGHTS WITHIN EURECA 9

3.1 Introduction 9

3.1.1 IP AND PROPRIETARY RIGHTS IN INFORMATION 10
3.1.2 PROPRIETARY RIGHTS IN PATIENT DATA IN EURECA 11

3.1.2.1 Use of data for research and profit 12
3.1.2.2 Authorizations on use 12

3.1.3 CONFIDENTIALITY OF PATIENT DATA 13
3.1.4 PATIENT DATA AS UNDISCLOSED INFORMATION 15

3.1.4.1 Legal framework 15
3.1.4.2 Defining undisclosed information 16
3.1.4.3 Patient data stemming from clinical trials 17
3.1.4.4 Right holders of patient data 21
3.1.4.5 Rights of right holders 21
3.1.4.6 Proposal for Trade Secret Directive 22
3.1.4.7 Conclusions and legal guidelines 24

3.1.5 CONFIDENTIAL PATIENT DATA, IP AND PROPERTY RIGHTS 25

3.2 IPR issues relating to EURECA repositories 26

3.2.1 DATABASE PROTECTION IN INTERNATIONAL TREATIES 27
3.2.2 DATABASE PROTECTION IN THE EU 28

3.2.2.1 Definition of “database” 28
3.2.2.2 Protection of databases under copyright 30
3.2.2.3 Protection of databases under the *sui generis* right 33

3.2.3 CONCLUSIONS FOR EURECA 36
3.2.4 LEGAL ANALYSIS OF USING EXTERNAL DATA SOURCES IN EURECA 38

3.2.4.1 Use of external data sources in EURECA 38
3.2.4.2 Copyright and licensing issues 39
3.2.4.3 Legal issues related to sui generis database right 44
3.2.4.4 Use of SNOMED CT 45
3.2.4.5 IPR regulations related to SNOMED CT 51

3.2.5 CONCLUSIONS 52

3.3 IPR issues relating to software and licensing 53

3.3.1 PROTECTION OF SOFTWARE 53
3.3.2 PROTECTION OF COMPUTER PROGRAMS UNDER COPYRIGHT 53

3.3.2.1 Protectable subject matter in EURECA 53
3.3.2.2 Legal framework 54
3.3.2.3 Basic criteria of protection by copyright 54
3.3.2.4 Object and scope of protection 56
3.3.2.5 Additional protection of software elements under know-how 57
3.3.2.6 Moral rights of the author 58
3.3.2.7 Conclusions for EURECA 59
3.3.2.8 Economic rights of the right holder 59

3.3.3 PROTECTION OF SOFTWARE UNDER PATENT LAW 61

3.3.3.1 Legal framework 61
3.3.3.2 Patentable subject matter in EURECA 62
3.3.3.3 Patentability criteria 63
3.3.3.4 Computer implemented inventions 64
3.3.3.5 Rights to a patent 66
3.3.3.6 Software patents and licensing issues 67
3.3.3.7 Conclusions 69

3.3.4 SOFTWARE LICENSING ISSUES WITHIN THE CONSORTIUM 69
3.3.5 SOFTWARE LICENSE AND ACCESS RIGHTS 69

3.3.5.1 Software license 69
3.3.5.2 Form of contract 71
3.3.5.3 Access rights for execution of the Project 71
3.3.5.4 Access rights for Use 72

3.3.6 SUBLICENSE TO END-USERS 73

3.3.6.1 Rights of end-users 73
3.3.6.2 Error correction 74
3.3.6.3 De-compilation 74
3.3.6.4 Conclusions 75

3.3.7 OPEN SOURCE SOFTWARE AND SOFTWARE LICENSING 75

3.3.7.1 Controlled License Terms 76
3.3.7.2 Use of external open source software 77
3.3.7.3 License and compatibility issues 79
3.3.7.4 Conclusions 81

3.3.8 LICENSING SOLUTION FOR EURECA..... 81

3.3.8.1 Open source license Apache License Version 2.0..... 82
3.3.8.2 Apache v2 license requirements 82
3.3.8.3 Apache v2 and patent rights..... 83
3.3.8.4 Apache v2 and license compatibility..... 83
3.3.8.5 Exploitation options 85
3.3.8.6 Conclusions 85

4 SUMMARY..... 87

1 Introduction

Where, as in the EURECA Project, the Partners spend a considerable amount of time and effort creating novel inventions, inevitably a question of the protection of invested resources appears. In law, such protection is offered mainly through the instruments of Intellectual Property Rights.

It is the goal of this deliverable to analyze the available legal protection and how the regime of IP can best fulfil the needs of the Project as a whole and of particular Partners. For this reason D7.4 shall examine the main applicable IP instruments and judge their usefulness against the envisaged outcomes of the Project.

An outcome should aid the Project Partners and the Consortium as a whole in further decisions for both exploitation and dissemination of EURECA results.

2 Decisions on intellectual property taken towards dissemination and exploitation

Current dissemination and exploitation decisions are bound to shape the Project now and in the future. As such, they will also shape the boundaries of the legal analysis of this Deliverable, just as the possible intellectual property rights in turn influence the decisions taken with regard to dissemination and exploitation.

For example, due to the decision of some partners to license software under an Apache license, this Deliverable takes a closer look at this license. On the other hand, the IP framework described here sets the path for dissemination and exploitation.

For that reason, this Deliverable first seeks to analyze the decisions taken in the two areas of dissemination and exploitation, which are part of WP10.

2.1 Decisions taken on dissemination

Dissemination, represented within the Project by WP10 is one of the major focal points where IPR come in question. *e*cancer has been chosen as the lead partner for dissemination activities, which is why their practice as regards licensing will briefly be presented.

*e*cancer is an Open Access Publisher and uses different Creative Commons licenses depending on the type of content being distributed and recommends that other project partners use the same licenses.

Videos and educational courses and modules, for example, are covered by the Attribution-NonCommercial-NoDerivatives 3.0 Creative Commons licence[1], which allows non-commercial use as long as the source is properly attributed, but does not permit derivative works, whereas written material and journal articles are covered by the Creative Commons Attribution 3.0 Unported license[2], pursuant to which content may be freely used by whomever, even commercially, as long as the source is appropriately attributed.

2.2 Decisions taken on exploitation

No unanimous decision was made regarding IP in the context of exploitation of EURECA results. Indeed, one of the salient characteristics of the initial exploitation plan (resubmitted in the D10.4 Initial exploitation plan) is the diversity of the partner's IP plans. For example, some partners are willing to release what they have produced as open source, while others prefer proprietary licensing models. As was established during the session of WP 7 in the Project meeting, which took place in Brussels in June 2014, some Partners are already committed to using an Apache license.

[1] Available at Creative Commons: http://creativecommons.org/licenses/by-nc-nd/3.0/legalcode.

[2] Available at Creative Commons: http://creativecommons.org/licenses/by/3.0/legalcode.

Nevertheless, an open source approach will most likely be selected for the platform itself, while individual tools will probably be released under proprietary licenses.

Notwithstanding the above, and for the sake of clarity, IPR decisions with regard to the exploitation of EURECA tools are dependent on the Grant Agreement (GA) and the Consortium Agreement (CA) terms and conditions.

Currently, many partners feel that it is still too early to make any formal commitment one way or another. Most likely, discussion with the partners involved will have to take place component by component when exploitation will be considered. Just as *e*cancer as an Open Access Publisher has made this their default approach to licensing, some individual partners – mostly academic centres – have as their default approach an open source licensing model.

3 Analysis of the most important Intellectual Property Rights within EURECA

3.1 Introduction

There are a wide variety of elements in EURECA that may enjoy protection as intellectual property. The goal of this Deliverable is to analyse how these elements may be protected under the intellectual property regime. As per the Description of Work (DoW), international and European legislation will be considered.[3] As part of its analysis, the deliverable will frequently refer to the EURECA legal framework as laid down by the Consortium Agreement (CA) and the Grant Agreement (GA). Best effort has been taken to account for changes that occurred through the Project progression since the DoW was written and to reflect the state of the Project as it is.

It is important to acknowledge that the IPRs arising in EURECA may be considered from two perspectives – the internal and the external one. The internal one governs the relations between the Partners in the Project and focuses, e.g., on the use of IPR protected matters of one Partner by another. The external perspective on the other hand is relevant when considering how the IPR arising from the Project shall be handled with third parties (non-Partners). This distinction can be seen as parallel to the IPRs governed within the Project lifetime opposed to the IPRs applicable after the Project ends.

On the other hand, also IPRs as such can be divided into subgroups that are more or less relevant in different Project stages. The Project's protectable elements can be classified into three distinct groups, which will be analysed separately and will form the main structure of the Deliverable.

(a) The first group is the patient data used in EURECA.

(b) The second category encompasses the repositories that EURECA will generate. Here, it is important to realize that once repositories qualify for protection as databases and contain data, the protection of contents, i.e. the data itself, is completely different and separate from the protection afforded to the database as a specific compilation of data.

(c) The third group is the software and software-related outcomes of the Project.

While the exact intellectual property rights (IPR) that need to be considered depend on the group being analysed, in general of particular relevance to the EURECA project as a whole are copyright in computer programs, patents, rights[4] in confidential information

[3] See DoW, Part A, p. 28.

[4] This Deliverable considers rights in know-how within the legal analysis of IPR. While this approach is not universally accepted, it is for example legislatively anchored in the TRIPS Agreement.

and know-how (undisclosed information[5]) and the *sui generis* database right as relating to patient data.

3.1.1 IP and proprietary[6] rights in information

This section will analyse whether the patient data, or certain data elements, used in EURECA can qualify as undisclosed information, what property rights may subsist in it and how it may be protected. The object and scope of protection as well as the right holders and protected rights will be identified.

When we deal with property rights in patient data, we treat the patient data as a type of information. The generic term *"information"* may refer to knowledge, intelligence or news, data or facts, collection of data or facts, etc.

"*Property rights in information have long been taken for granted (…) in most of the developed world*"[7]. When the value of information for society exceeds its development costs, the production of information becomes socially desirable.

This ties in with how data from clinical trials is required to be made public in many jurisdictions.

"*When researchers embark on a clinical trial, they make a commitment to conduct the trial and to report the findings in accordance with basic ethical principles. This includes preserving the accuracy of the results and making both positive and negative results publicly available*"[8].

"The solution for balancing the social need in information with the interests of the entities in producing such information is "an intellectual property rights regime (…). composed primarily of copyright and patent law, but also encompassing trademark and trade secret protection"[9].

---

[5] There is no uniform definition of the terms "know-how", "trade secret" and "undisclosed information". For the purposes of this Deliverable all three terms are used as synonyms unless otherwise indicated.

[6] In this Deliverable "proprietary" and "property" rights are used as synonyms, both relate to the exclusive rights of the persons, which hold the patient data in lawful possession and control, and which are explicitly granted and protected by the law.

[7] Calandrillo S.P., "An Economic Analysis of Property Rights in Information: Justifications and Problems of Exclusive Rights, Incentives to Generate Information, and the Alternative of a Government-Run Reward System", 9 Fordham Intell. Prop. Media & Ent. L.J. 301, 303 [1998], available at: http://ir.lawnet.fordham.edu/cgi/viewcontent.cgi?article=1194&context=iplj.

[8] WHO, Reporting the findings of clinical trials: a discussion paper, available at: http://www.who.int/bulletin/volumes/86/6/08-053769/en/

[9] Calandrillo S.P., supra.

Protection of Commercially Confidential Information (CCI) is also envisaged by the Policy on publication of clinical-trial data, being developed by the European Medicines Agency (the EMA)[10]. "*The Agency respects and will not divulge commercially confidential data or information. In general, however, CT data cannot be considered CCI; the interests of public health outweigh considerations of CCI*"[11]. The Policy supports such key principles as: editing clinical study reports appropriate for publication, development of methodology for de-identification of patients and definition of standard format for the submission of data[12]. The LUH has been nominated to be among the Members of Clinical Trials Advisory Groups as related to the legal aspects[13].

For the patient data used in EURECA, the following rights are of relevance:

- Rights in confidential information, relating to the patient data which are treated as confidential, but do not stand the criteria of undisclosed information, , as will be analysed below;

- Rights in undisclosed information, relating to certain elements of the patient data which are treated as confidential plus stand the criteria for protection, as will be considered in detail below;

- The *sui generis* database right, relating to the mass of data which constitute a substantial part or the whole contents of a repository. This type of protection may be applicable to data, provided the repository itself qualifies for protection under the sui generis database right.

3.1.2 Proprietary rights in patient data in EURECA

As per the DoW, *"[a]vailability of a sufficient volume (and variety) of clinical data is essential to the success of ICT research projects in the healthcare and clinical domain"*[14]. Hence, EURECA patient data serve primarily as the fuel of the Project, without which no results could be generated.

---

[10] EMA, Transparency, Releasing clinical-trial data, Publication and access to clinical-trial data: an inclusive development process, available at: http://www.ema.europa.eu/ema/index.jsp?curl=pages/special_topics/general/general_content_000556.jsp.

[11] EMA, Science Medicines Health, Publication and access to clinical-trial data, 24 June 2013, EMA/240810/2013, available at: http://www.ema.europa.eu/docs/en_GB/document_library/Other/2013/06/WC500144730.pdf.

[12] EMA, Publication and access to clinical-trial data: an inclusive development process, supra.

[13] EMA, Clinical Trial Advisory Groups, Membership overview – 20 February 2013, available at: http://www.ema.europa.eu/docs/en_GB/document_library/Other/2013/01/WC500137362.pdf.

[14] DoW, Section 1.2.23 Collaborative Project, Part B, p.51.

Use of patient data in EURECA is governed by the CA. Indeed, patient data are specifically contributed to the Project by the individual data providers and will be used for the development of tools and evaluation/validation purposes only.[15]

3.1.2.1 Use of data for research and profit

The permitted uses of patient data are set forth in Section 4.1.5.1 CA. according to which:

"Patient Information Contributor hereby authorizes and allows all Parties receiving Patient Information from Patient Information Contributor to use the Patient Information for research, development, other legitimate business purposes, including submission to regulatory bodies, education and publication, excluding any commercial use".

As explicitly stated, use of patient data contributed to the Project on commercial scale is explicitly excluded. However, as far as patient data are not concerned, it does not affect exploitation options of services and ICT tools, developed in EURECA, which enjoy separate legal regime and for which commercial options may be allowed, provided other restrictions, e.g. as may be dictated by the license, do not apply.

Use and exploitation of patient data, as governed by Article 4.1.5 CA, is not interrelated with the use and exploitation of IPR and Foreground, generated by the Project, as subject to the rules on Intellectual Property Rights and Access Rights, namely Section 4.2 CA. Both the definition of Background and Foreground, which are subject to the rules on Access Rights, do not include Patient Information, as explicitly defined by Article 1.2 CA.

Furthermore the Contracts signed by all the Data Providers and End Users for reasons of privacy protection limit the scope of the data use and allow the use of the data for research purposes only.[16]

The question whether the Data Providers themselves may use their own de-identified patient data commercially outside of EURECA is beyond the scope of this Deliverable

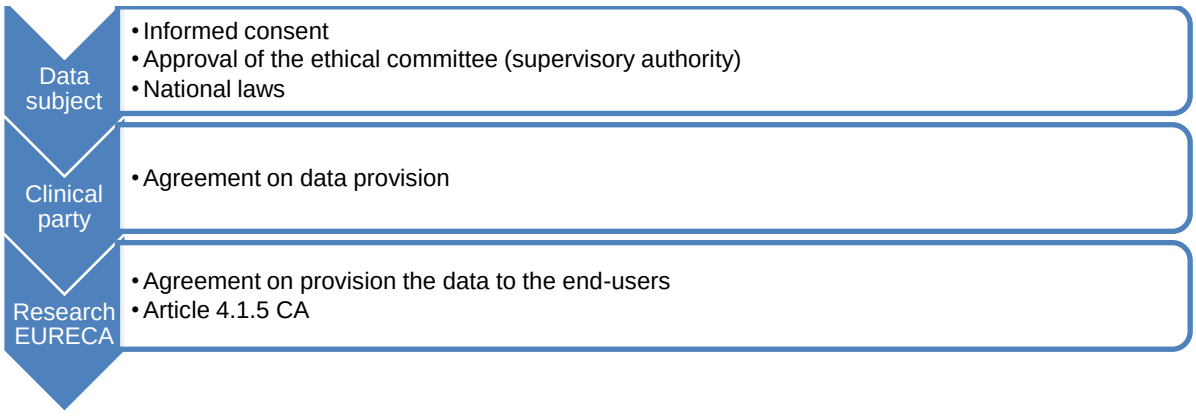
3.1.2.2 Authorizations on use

The chain of authorized data use is as follows:

Figure 1: Chain of reuse of the patient data for research.

[15] Ibid.

[16] See: D7.1 Initial EURECA legal and ethical requirements, Annex 1.



To sum up, use, scope and purpose of use of patient data in EURECA and further research shall stay compliant with the provisions of the law on data protection and be based on legitimate grounds, (i.a. informed consent of the data subject, approval of the respective Ethics Committee).

3.1.3 Confidentiality of patient data

As follows from the DoW[17] and established within the Project progression, the patient data comes from trials and studies conducted by the clinical parties or affiliated institutions and home-grown EHR of the clinical parties[18]. The clinical parties collect and host the patient data themselves via running their research or healthcare activities, as legally authorized. On these grounds it is expected that the clinical parties hold the patient data in their lawful possession and control. The data shall be supplied for the Project in compliance with the legal requirements, set out in Article 4.1.5.1 CA, meaning that the data will be provided as de-identified. Patient data may come either in raw format (e.g. text data from the EHR, clinical trials and studies) or as integrated into the databases (e.g. databases run by the clinical partners).

Personal data relating to health is subject to a special regime of procession, as laid down in Article 8 of the Directive 95/46/EC[19]. Due to policy regulations that govern use of personal data in the clinical and healthcare domain[20], in particular the Good Clinical Practice Directive[21], the clinical parties are bound to keep such data confidential and

[17] DoW, Section 1.2.23 Collaborative Project, Part B, p.51.

[18] Ibid.

[19] Directive 95/46/EC of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data

[20] The Declaration of Helsinki; internal regulations of the clinical partners, etc., as defined in Article 4.1.5.1 CA.

[21] Directive 2001/20/EC of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use; Directive

protected from unlawful use and disclosure. Due to the confidentiality regime, mandated for the personal data in clinical domain by the law, the patient data shall, in general, neither be available to the general public nor to any other recipient dealing with the information in question. Even when disclosure of clinical trials, including research ones, to the public is prescribed[22], still the competent authorities only[23] shall have access to the data and "*the confidentiality of the data (…) shall be strictly observed*"[24].

It follows, that prior to entering into the Project, the patient data coming from clinical and healthcare domains must have been kept strictly confidential and the Parties are bound to keep the data secret and take measures to ensure that secrecy of the data is observed.

With respect to treating patient data as confidential, it must be said that confidentiality of data, as dictated by the privacy or policy purposes, is different from protecting undisclosed information, motivated by commercial or competitive considerations and as supported and provided by the law. However, preserving confidentiality may be one of the steps and pre-requisites to protect the data as "*undisclosed information*" as well. For instance, in order to be treated as confidential in the Project, it may be sufficient when the data are supplied marked as "Confidential" and have not been made publicly available or accessible or developed by the receiving Parties before[25]. However, when other legal requirements are not fulfilled, these pre-cautions may not be enough so that the data can be protected as "*undisclosed information*" by the law. To be protected as "*undisclosed information*", such criteria as "secrecy", "economic value" and *"adoption of confidentiality measures",* as determined by legal provisions, must be fulfilled.

First, we consider the scope of confidentiality of information, as governed for the Project and as may be relevant for legal protection too. Protection of patient data as "*undisclosed information*" will be analysed in more detail below.

Confidentiality of information in the meaning of CA is more or less similar to the substance of "*secrecy*", as defined for undisclosed information by the law. . In general, it means that the information (or data sets) in question shall not have been accessible to the public or to the receiving party before the disclosure and that disclosure must have been subject to the contractual duty to keep the data secret. Another pre-requisite of protection is the criterion of economic value. This factor is not provided for in the CA. The information may be considered as having the economic value when

2005/28/EC of 8 April 2005 laying down principles and detailed guidelines for good clinical practice as regards investigational medicinal products for human use, as well as the requirements for authorization of the manufacturing or importation of such products.

[22] Article 11 Directive 2001/20/EC.

[23] Article 11 Paragraph 1 Directive 2001/20/EC

[24] Article 11 Paragraph 3 Directive 2001/20/EC.

[25] Article 4.3.3 CA.

competitiveness of the entity, which holds the information in question, may be weakened once the information is revealed[26].

The main legal regime which we consider as applicable to protect rights in the patient data, to be more precise, certain datasets of the data, is the regime of undisclosed information.

3.1.4 Patient data as undisclosed information

3.1.4.1 Legal framework

The main international legal treaty that provides for protection of undisclosed information is the World Trade Organisation's 1994 Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement). The TRIPS Agreement requires WTO members – and as such also the EU – to introduce a certain minimum standard of protection for intellectual property as defined in the Agreement.[27]

The protection of undisclosed information is regulated in Article 39 TRIPS Agreement and shall be applied by the Member States as a measure to ensure "*effective protection against unfair competition as provided in Article 10bis of the Paris Convention (1967)*"[28].

On the EU level the legal protection of undisclosed information is not harmonized. Know-how is dealt with by the Commission Regulation (EC) No 772/2004 of 27 April 2004 on the application of Article 81(3) of the Treaty to categories of technology transfer agreements. However, the Regulation applies to technology transfer agreements concerning licensing of technology in competition matters[29] and does not cover protection of know-how in general. There is an ongoing initiative on harmonization of the protection of know-how in the EU. As of now, the Proposal for a Directive on the protection of undisclosed know-how and business information (trade secrets) against their unlawful acquisition, use and disclosure[30] is made available for consultation. Because there is no uniform legal regulation of undisclosed information in the EU, the main legal basis for legal analysis here will be the TRIPS Agreement, the draft of the Directive will be analyzed briefly as well.

---

[26] Hogan Lovells LLP, Report on Trade Secrets for the European Commission, Study on Trade Secrets and Parasitic Copying (Look-alikes) MARKT/2010/20/D, available at: http://ec.europa.eu/internal_market/iprenforcement/trade_secrets/index_en.html.

[27] Article 1Paragraph TRIPS Agreement.

[28] Article 39(1) TRIPS Agreement.

[29] Recital 5 Commission Regulation (EC) No 772/2004 of 27 April 2004 on the application of Article 81(3) of the Treaty to categories of technology transfer agreements.

[30] Proposal for a Directive of the European Parliament and of the Council on the protection of undisclosed know-how and business information (trade secrets) against their unlawful acquisition, use and disclosure /* COM/2013/0813 final - 2013/0402 (COD), available at: http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:52013PC0813.

The provisions governing protection of know-how and rights in it under the national laws vary and may be spread among multiple legal acts. Know-how may enjoy protection under the competition laws (e.g. Disclosure of trade and industrial secrets, Paragraph 17 Unfair Competition Act of Germany[31], Paragraph 11 Unfair Competition Act of Austria[32]), the law of confidence (UK and Ireland[33]) as well as criminal, labor, tort, contract laws.

3.1.4.2 Defining undisclosed information

Patient Data may qualify for protection as undisclosed information provided they stand the criteria, as laid down in Article 39 Paragraph 2 TRIPS Agreement. Protection applies to information which:

"(a) is secret in the sense that it is not, as a body or in the precise configuration and assembly of its components, generally known among or readily accessible to persons within the circles that normally deal with the kind of information in question;

(b) has commercial value because it is secret; and

(c) has been subject to reasonable steps under the circumstances, by the person lawfully in control of the information, to keep it secret".

Consequently, the data which satisfy these requirements may be classified as undisclosed information. The substance of data which may constitute "undisclosed information" is not defined. Several types of information are considered as capable to be protected as "undisclosed information" in the EU, including but not limited to: industrial and commercial data, technical and non-technical data, including methods, techniques, financial data, lists of customers and suppliers. R&D information, negative information (e.g. processes which have been discovered not to work) and genetic material are also included into the protectable subject matter in some EU Member States[34].

Apart from the requirements of protection, stated above, and types of information which can be classified into know-how by the Member States, in legal terms the term "undisclosed information" is not defined.

Know-how, applicable to technology transfer agreements, is defined as:

---

[31] "Gesetz gegen den unlauteren Wettbewerb in der Fassung der Bekanntmachung vom 3. März 2010 (BGBl. I S. 254), das zuletzt durch Artikel 6 des Gesetzes vom 1. Oktober 2013 (BGBl. I S. 3714) geändert worden ist" (UWG), available at: http://www.gesetze-im-internet.de/uwg_2004/BJNR141400004.html

[32]Bundesgesetz gegen den unlauteren Wettbewerb 1984 - UWG, available at: https://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen&Gesetzesnummer=10002665

[33] Hogan Lovells LLP, supra.

[34] Hogan Lovells, supra, p. 35.

"a package of non-patented practical information, resulting from experience and testing, which is: (i) secret, that is to say, not generally known or easily accessible, (ii) substantial, that is to say, significant and useful for the production of the contract products, and (iii) identified, that is to say, described in a sufficiently comprehensive manner so as to make it possible to verify that it fulfils the criteria of secrecy and substantiality"[35].

In substance, the term is similar to that of undisclosed information provided in TRIPS Agreement. However, what can be concluded from the legal provisions dealing with "undisclosed information" or "know-how" above, is that the data in question must be identifiable as a "*package*" or "*as a body or in the precise configuration and assembly of its components*"[36].

There are also additional factors which come from the court practice of EU Member States and may be taken into account. Such factors include:

> *"(a) the extent to which the information is known outside;*
>
> *(b) the extent to which the information is known by employees and others involved in the owner's business;*
>
> *(c) the measures taken by the owner to guard the secrecy of the information;*
>
> *(d) the value of the information to the owner and to its competitors;*
>
> *(e) the amount of effort or money contributed by the owner to develop the information;*
>
> *(f) the ease or difficulty with which the information could be acquired or duplicated by others"*[37].

3.1.4.3 Patient data stemming from clinical trials

The patient data for the Project derive from the clinical trials, conducted for research. The patient data or certain datasets obtained from the clinical trials for research may qualify for protection as undisclosed information in the meaning of Article 39 (2) TRIPS Agreement, provided they stand the criteria of protection, as will be analysed below.

3.1.4.3.1 *Secrecy*

To stand the criterion of secrecy the clinical data must not be, *"as a body or in the precise configuration and assembly of its components, generally known among or readily accessible to persons within the circles that normally deal with the kind of*

[35] Article 1 (i) Regulation No 772/2004 of 27 April 2004 on the application of Article 81(3) of the Treaty to categories of technology transfer agreements (Text with EEA relevance).

[36] Article 39 Paragraph 2 (a) TRIPS Agreement.

[37] Hogan Lovells, supra, p. 39.

information in question"[38]. In the case with the clinical trials, *"persons within the circles that normally deal with the kind of information in question"* should mean researchers and professionals from the domain of medical research and healthcare.

Any publication of the data will remove its status of being secret[39]. This is particularly relevant for the results from clinical trials, which due to the policy regulation and purposes of transparency must be made public. The transparency requirement relates also to the clinical trials for research, the results of which must be reported *"in accordance with basic ethical principles. This includes preserving the accuracy of the results and making both positive and negative results publicly available"*[40].

Disclosure of the clinical trials results may occur through publication in scientific literature (e.g. peer reviewed magazines) or clinical trial databases and registries (e.g. U.S. National Institutes of Health at www.clinicaltrials.gov, the UK Current Control Trials at www.controlled-trials.com).

The data to be published are, in general, limited to formal and rather general data, as for instance set out by The Trial Registration Data Set (TRDS), Version 1.2.1, established by the WHO[41], and may vary from registry to registry Publication of such data shall provide general information on the trial, intervention type, clinical subjects concerned, outcomes, etc. Certain data items, not triggered by mandatory registration, might be concealed from disclosure and be considered for further protection. To be considered for protection the data sets concerned shall be identified "*as a body or in the precise configuration and assembly of its components*"[42]. Hence, in order to preserve these data confidential, the identified data sets shall be marked as "Confidential". Another step would be to subject such data to the reasonable steps to keep them secret, as will be discussed below.

3.1.4.3.2 *Steps to keep information secret*

Apart from the fact that the data sets in question must not have been made accessible to the public or persons within professional circles "*that normally deal with the kind of information in question"*[43], the datasets concerned must have been "*subject to*

[38] Article 39 para 2 TRIPS Agreement.

[39] Lodigkeit K., Intellectual Property Rights in Computer Programs in the USA and Germany, 2005, p. 98.

[40] WHO, International Clinical Trials Registry Platform (ICTRP), Reporting of Findings of Clinical Trials: a discussion paper, available at: http://www.who.int/ictrp/results/en/.

[41] WHO, International Standards for Clinical Trial Registries, 2012, available at: http://www.who.int/about/licensing/copyright_form/en/index.html.

[42] Article 39 Paragraph 2 (a) TRIPS Agreement.

[43] Ibid.

reasonable steps under the circumstances, by the person lawfully in control of the information, to keep it secret"[44].

A contractual duty to keep the data secret can be sufficient. As established by the Court of Appeals Hamm in Germany[45], "*the agreement that the information shall not be passed to the outsiders can be sufficient for maintaining secrecy*"[46].

The steps to preserve secrecy of data might be to identify circle of persons, inside the institution, which conducts the clinical trials, e.g. employees, professionals, researchers and other persons, who are involved in the conduct of clinical trials and have access to the data. The persons concerned shall be bound by the contractual duty to keep such data sets secret, to use the data according to the terms and purpose of use and bear liability for unauthorized access, use or disclosure. The confidentiality obligations may be incorporated either in an employment agreement, or contract for services, or another contractual type regulating relations with these persons, or be imposed under a separate confidentiality or non-disclosure agreement.

Further, the clinical parties may define the scope in how far and by whom the protected data items may be used outside, e.g. specify the persons who might be granted access to the data (e.g. affiliated research institutions), to subject disclosure of the data to the contractual duty to keep such data secret, specify the scope, purpose and terms of use, provide for contractual sanctions for any breach of the confidentiality obligation or misuse of the data, etc.

As regards release of the secret data in the Project, this criterion may be realized via supply of such data marked as "Confidential" following the Confidentiality provisions in CA set out in Section 4.3.

All in all, the more value the Parties attribute to the data, the more precautions and measures they take in order to preserve the data secret and maintain the data within their lawful control, the higher the chances are that the data and the rights of the Parties in the data will be recognized as protected.

3.1.4.3.3 *Economic value*

Another requirement for protection is that the information in question must have economic value because it is secret, as prescribed in Article 39 Paragraph 2 (b) TRIPS Agreement.

There is no unified approach in considering what quality renders the information of an economic value.

Since protection of undisclosed information is first of all a measure *"against unfair competition"*[47], a common approach that competition law adopts to determine whether

[44] Article 39 Paragraph 2 (c) TRIPS Agreement.

[45] Lodigkeit, supra, p.99; OLG Hamm, Urteil v. 1.9.1992, Tierohrmarken, WRP 1993, 36-38.

[46] Lodigkeit, supra, p.99.

the data has economic value is proving whether the "*owner has an economic interest in keeping the facts secret, which is present when the competitiveness of the company could be weakened through publication of the facts*"[48].

Improper disclosure of patient data could jeopardize the competitive standing of the clinical parties in the medical research domain and be detrimental to their reputation. Taken that the patient data has the status of personal data, the interest in protecting the data from improper access and disclosure, not only because of the policy regulations, but also because of own R&D and reputational concerns, seems to be obvious.

The clinical parties are represented by renowned research institutions in the cancer domain, which have long term expertise and good standing in research and treatment of cancer. The reputation of the clinical parties is built through long term R&D work, experience in research and patient care. This knowledge and experience is reflected in scientific publications and the volumes of patient data built up. For example, if the clinical trials are conducted within a long term R&D work focusing on treatment of a particular cancer type, the clinical findings might be essential and envisaged for a scientific publication. The same may concern positive and negative findings which make up knowledge on cancer treatment which can only be gained from long term research and experience and clinical trials conducted, and in no other way. As mentioned, the so-called negative information, covering methods which proved not to work, are recognized by some EU Member States as a type of protectable know-how[49]. The data on treatments tested through the clinical trials and discovered not effective can therefore also be considered as protectable subject matter. Such findings do make an essential part of the expertise of the clinical institution, which could be gained through long term work and effort only.

From these observations it can be concluded that the findings of clinical trials are important for the academic and professional standing of the clinical parties in the cancer research and treatment. Against this background and apart from the policy regulations, interest of the clinical parties to hold the patient data in control and protect against improper disclosure is to large extend dictated by the concerns of preserving and building own reputation.

Certain elements from the patient information, contributed to EURECA, are supposed to have the quality of undisclosed information, as provided for by Article 39 Paragraph 2 TRIPS Agreement, once the measures to keep such data elements confidential are in place. The parties, which applied such protective measures, shall enjoy protection, granted to know-how.

---

[47] Article 39 Paragraph 1 TRIPS Agreement.

[48] Lodigkeit, supra, p. 101.

[49] Hogan Lovells, supra, p. 35.

3.1.4.4 Right holders of patient data

Pursuant to Article 39 Paragraph 2 TRIPS Agreement the right of preventing information from unauthorized access, use and disclosure is assigned to the *"natural and legal persons"* who hold the protectable information "*lawfully within their control".* The clinical parties as research institutions are supposed to be established and have the status of legal persons.

As regards holding the information "*lawfully within their control",* the status of the patient data as gained and kept lawfully by the clinical parties may be derived from Article 4.1.5.1 CA. It says: "*The Patient Information Contributor warrants that it has obtained the Patient Information with due observance of the rights of the patients involved and in compliance with all applicable laws and regulations".* From this provisions follows, that the data providers must have collected the patient data, which they supply to the Project, by their legitimate activities and keep such data in their legitimate possession and control.

Following these considerations it may be concluded that the clinical parties may have the status of right holder in relation to the patient data (data items), which might qualify as undisclosed information.

3.1.4.5 Rights of right holders

Rights in the undisclosed information are provided in Article 39 Paragraph 2 TRIPS Agreement. The holders of undisclosed information shall have the right to "*prevent information from being disclosed to, acquired by, or used by others without their consent in a manner contrary to honest commercial practices".*

A legal regime of undisclosed information is considered to be a measure against unfair competition[50]. It shall protect information from being appropriated or used "*in a manner contrary to honest commercial practice"*[51]*.* What activities are considered as "*contrary to honest commercial practice"* is explained in the Footnote 10 to Article 39 TRIPS Agreement. These activities include such acts as: *"breach of contract, breach of confidence and inducement to breach, (…) acquisition of undisclosed information by third parties who knew, or were grossly negligent in failing to know, that such practices were involved in the acquisition"*[52]*.* Considering that protection of undisclosed information is prescribed as a measure against unfair competition[53], such practices usually relate to anti-competitive practices, such as: unauthorised disclosure of trade or industrial secrets "*for the purposes of competition, for personal gain, for the benefit of a third party, or with the intent of causing damage to the owner of the business*"[54], e-g- stealing business secrets, selling commercial information to a competitor, etc.

---

[50] Article 39 Paragraph 1 TRIPS Agreement.

[51] Article 39 Paragraph 2 TRIPS Agreement.

[52] Footnote 10 to Article 39 TRIPS Agreement.

[53] Article 39 Paragraph 1 TRIPS Agreement

[54] Section 17 Paragraph 2, Gesetz gegen den unlauteren Wettbewerb (UWG), supra.

However, how the rights in the undisclosed information may be enforced in practice varies from country to country. Legal remedies range from sanctions provided by the competition, labour, tort and criminal laws to injunctions, damages and search orders[55].

"In the UK and the Republic of Ireland there is no legislation to protect trade secrets and the breach of confidence action is the principal means of trade secret protection. A plaintiff will be required prove that the information has the necessary quality of confidence, that it was imparted in circumstances of confidence and there has been (or is threatened) misuse or disclosure of the information"[56]. Once damages are claimed, that plaintiff shall prove that *"...the misuse or disclosure has caused (or will cause) damages. Most, if not all, States provide for the protection of trade secrets by contractual obligations"*[57].

Due to the not established practice of protecting know-how in EU, a legal remedy which is most likely to be available in most EU Member States would be breach of confidence and breach of contract. The remedy of contractual claims and breach of confidence protects the patient data of the clinical parties of EURECA.

3.1.4.6 Proposal for Trade Secret Directive

The draft directive, of which the full name reads "Proposal for a Directive on the protection of undisclosed know-how and business information (trade secrets) against their unlawful acquisition, use and disclosure" (Draft Directive), is part of the Europe 2020 strategy. The draft is based largely on the TRIPS Agreement. It aims at improving the condition for innovative business activities by "*protecting investments in the knowledge base, reducing costly fragmentation, and making Europe a more rewarding place for innovation*."[58]

That trade secrets are an important element within the economy is widely recognised. They are a result of previous investments and as such represent a competitive advantage, hence their protection is crucial, especially to small and medium-size firms which may not be capable of securing the registered IPRs.

One reason behind the Commission's decision is the current fragmentation of the protection offered to trade secrets by Member States. An envisaged gain is to make it

[55] Hogan Lovells, supra, p. 40.

[56] Hogan Lovells, supra, p.37.

[57] Ibid.

[58] Proposal for a Directive on the protection of undisclosed know-how and business information (trade secrets) against their unlawful acquisition, use and disclosure, Explanatory Memorandum of the Proposal, p. 2.

easier for the victims of trade secret misappropriation to obtain redress in European courts.[59]

In article 2[60] the Draft defines trade secrets, as:

> *"information which meets all of the following requirements:*
>
> *(a) is secret in the sense that it is not, as a body or in the precise configuration and assembly of its components, generally known among or readily accessible to persons within the circles that normally deal with the kind of information in question;*
>
> *(b) has commercial value because it is secret;*
>
> *(c) has been subject to reasonable steps under the circumstances, by the person lawfully in control of the information, to keep it secret."*

Acquisition of such trade secrets is unlawful whenever the acquisition falls into a category of conducts which are *"contrary to honest commercial practices."*[61] The Draft brings here instances such as theft or bribery, but also breach of confidentially agreements.

On the other hand, the Draft Directive makes it possible to lawfully acquire, use and disclose trade secrets, as long as it is done in accordance with *"honest commercial practices"*.[62]

Overall, the Proposal broadly follows the scheme of protection introduced by the TRIPS Agreement and re-introduces the already mentioned terms to the European legal bloodstream. As such, the status quo after the adoption of the Draft Directive will not change dramatically. Furthermore, it should be noted that the European Commission assumes that the adoption of the text by the European Parliament and the Council could take place by the end of 2014.[63] The standard transposition period is

---

[59] Compare: The European Commission Press release: „Commission proposes rules to help protect against the theft of confidential business information", 28.11.2013. Available at: http://europa.eu/rapid/press-release_IP-13-1176_en.htm.

[60] The provisions are comparable to those of Article 39 of TRIPS Agreement.

[61] Article 3 of the Draft.

[62] Article 4 of the Draft.

[63] Compare: Implementation Plan Accompanying the document Proposal for a Directive of the European Parliament and of the Council on the protection of undisclosed know-how and business information (trade secrets) against their unlawful acquisition, use and disclosure, available at:

http://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:52013SC0493&from=EN.

assumed once the Directive is adopted, [64] this means 24 months, which makes the applicability of the Directive to the EURECA Project highly unlikely.

3.1.4.7 Conclusions and legal guidelines

Within the legal analysis above it was established that the legal substance of the patient data is rather obscure. The data, especially when obtained from clinical trials, may relate rather to R&D information or personal data relating to health, than to technical, economic or commercial data, which are treated as know-how in the traditional sense. Certain datasets that comprise essential information on the clinical trials and outcomes, which have scientific or medical value, must already have been made public by the Parties, either in scientific literature or public registries of clinical trials. These aspects may hinder to qualify the patient data, taken in the whole volume, as undisclosed information in legal terms.

On the other hand, due to scientific, research or reputational concerns, some data elements, which have not been exposed to the public and are of a specific - scientific or professional - value for the clinical parties, may still be considered as protectable subject matter in the meaning of Article 39 TRIPS Agreement (i.e. undisclosed information), once protective measures are applied.

Also due to a lack of harmonized legal governance of know-how in the EU, whether the national courts of the EU Member States will view such qualification positively and will be willing to enforce the rights in such data under the legal regime of know-how is questionable. On the other hand, as was established from the court practice of the EU Member States[65], irrespective whether the information in question qualifies as know-how, contractual remedies and breach of confidence action shall be among the legal remedies available to enforce the rights in the information which was subject to the contractual duty to keep it secret.

Against this observation, the steps taken to keep the patient data confidential and applying protective measures, at least contractual obligations to keep the data secret, are considered as legally reasonable and recommended for the clinical parties in order to hold the patient data in control and preserve their rights in it. .

As regards the contractual regime of keeping the data confidential, a confidentiality regime may be imposed by signing a non-disclosure or confidentiality agreement. For securing confidentiality of data, the agreement shall i.e. identify what data have the status of Confidential Information, for what scope, term purpose and upon what terms the data are provided into use, what obligations the receiving party has in relation to using the data and keeping these confidential, etc. Sanctions and contractual penalties for breach of confidence as well as the applicable law and court which will try a breach of confidence action shall be agreed. It may be noted that proceedings under the general jurisdiction shall be public. Hence, for the purposes of preserving confidentiality of patient data during the court proceedings arbitral clause and subjection of the disputes in relation to such data may be considered.

---

[64] Ibid.

[65] Hogan Lovells, supra.

On the basis of the legal analysis conducted above, the legal guidelines for the holders of patient data interested in protecting such data under the legal regime of undisclosed information would be:

(a) To identify the data/data items which have not been revealed to the public or professional circles, which are important for the clinical party due to economic or reputational concerns and must be kept in control and secrecy;
(b) To mark such data/data items as “confidential";
(c) To stipulate the circle of persons which have access to the data and bind these persons by a contractual duty to keep the data secret, before the data are disclosed
(d) To release the patient data to such persons only upon signing the confidentiality agreement and accepting the contractual obligations to use the data strictly in accordance and for the purpose stipulated in the agreement and to keep the data secret;
(e) To stipulate the scope, purpose and terms of use of the data, rights and obligations of the receiving party in relation to the data;
(f) To provide liability and sanctions for the breach of confidence. To agree the applicable law and the court which shall pursue a breach of confidence action (arbitral clause).

3.1.5 Confidential patient data, IP and property rights

As regards treating confidential information as a type of IP, the following can be said. *“The TRIPS Agreement treats ‘undisclosed information’ as a form of intellectual property. Notwithstanding this, most Member States do not treat trade secrets as intellectual property”*[66] with some exceptions. Also trade secrets are not included into the list of IP rights covered by the Directive 2004/48/EC on the enforcement of intellectual property rights, as provided in the Statement by the Commission concerning Article 2 of Directive 2004/48/EC of the European Parliament and of the Council on the enforcement of intellectual property rights[67].

It follows that there is no uniform approach for treating undisclosed information as object of IP rights in the EU. On the other hand, since some national jurisdictions, in particular: Italy, France, Latvia, Slovenia, and to some extent England, tend to recognize know-how as part of IPR[68], claiming IP rights in the patient information, treated as confidential, will be subject to national jurisdictions concerned.

[66] Hogan Lovells, supra, p. 38.

[67] Statement by the Commission concerning Article 2 of Directive 2004/48/EC of the European Parliament and of the Council on the enforcement of intellectual property rights, available at: http://ec.europa.eu/internal_market/iprenforcement/directive/index_en.htm.

[68] Hogan Lovells, supra, p. 38.

As regards property rights, it is also arguable that confidential information may be considered as "property".

Article 1 of the European Convention on Human Rights provides: "*every natural or legal person is entitled to the peaceful enjoyment of his possessions"*[69]. As commented by the English Court of Appeal, "*The concept of 'possessions' is broad and covers a wide range of things which have significant economic value. It extends to business goodwill and to various forms of intellectual property, including copyright, although there is apparently no case which expressly covers confidential information (…) Although the parties were unable to cite any Strasbourg authority which expressly covers confidential information as a form of 'possessions, no case was cited against that proposition. I can see no reason, in the light of the Strasbourg jurisprudence which does exist, why valuable commercial information (…) cannot fall within the concept of 'possessions'"*[70].

The said judgment mentions "*valuable commercial information"* which under circumstances may still qualify as "possession". However, this does not mean that confidential information that does not have commercial value can qualify as type of possession.

3.2 IPR issues relating to EURECA repositories

One of the main goals of the EURECA Project is to be able to more efficiently collect and organize de-identified patient data directly from clinical settings and make it available to research, as well as being able to quickly transfer relevant research back to practitioners (the so-called "bench to bedside" approach).

Consequently, data repositories play a major role in the Project. Technically speaking, data repositories are collections of individual data strings arranged in a certain manner.

In legal terms, data repositories are generally classified as *databases*. This part of the Deliverable will therefore focus on the protection afforded to databases.

Databases are protected according to one of three basic systems that differ in whether only originality and creativity are recognized as worthy of protection or also other types of investments, such as time and money.[71]

Granting copyright protection even where creativity is lacking, in recognition of the investments which were made in order to compile a database – the so-called "sweat of

[69] European Convention on Human Rights as amended by Protocols Nos. 11 and 14 supplemented by Protocols Nos. 1, 4, 6, 7, 12 and 13.

[70] Lovells, supra, p. 38; Veolia v Nottinghamshire CC [2010] EWCA Civ 1214.

[71] Such a categorization is by design rather simplistic, but it nevertheless grants a good overview of the systems in place through the world. See Mark J. Davison, *The Legal Protection of Databases*, Cambridge Studies in Intellectual Property Rights (Cambridge: Cambridge Univ. Press, 2003), p. 10.

the brow principle". This is typical for most common law countries with the exception of the United States.[72]

Granting copyright protection to compilations which contain some level of creativity and having a separate *sui generis* protection for databases lacking originality but compiled using other types of investments.[73] This model is used in the EU.

Granting copyright protection to works which possess a certain creativity and owe their existence to an "act of authorship"[74], as in the United States.

Some jurisdictions also apply the rules of unfair competition and also competition law[75] to the protection of databases.[76] Their analysis will be excluded from this Deliverable, as such protection is regulated on a purely national basis.

3.2.1 Database protection in international treaties

On the international level, databases are given protection under copyright regimes. The European Union is party to three treaties that give databases protection:

- The Berne Convention for the Protection of Literary and Artistic Works ("Berne Convention"),
- The WIPO Copyright Treaty ("WCT"), and
- The TRIPS Agreement.

However, the Berne Convention is excluded from the scope of this analysis because it is only applicable to collections of literary and artistic works.

The TRIPS Agreement requires WTO members – and as such also the EU – to introduce a certain minimum standard of protection for intellectual property as defined in the treaty.[77] Regarding databases, Article 10(2) TRIPS Agreement states that:

"*[c]ompilations of data or other material, whether in machine readable or other form, which by reason of the selection or arrangement of their contents constitute intellectual creations shall be protected as such. Such protection, which shall not extend to the data or material itself, shall be without prejudice to any copyright subsisting in the data or material itself.*"

---

[72] Ibid.

[73] Ibid.

[74] David I. Bainbridge, *Introduction to Information Technology Law*, 6th ed. (Harlow: Pearson Longman, 2008), p. 73.

[75] Understood as abuse of market power.

[76] See Davison, *The Legal Protection of Databases*, pp. 37 et seqq, pp. 43 et seqq.

[77] See Article 1(1) TRIPS Agreement.

Similarly, the WCT states in Article 5 that:

"[c]ompilations of data or other material, in any form, which by reason of the selection or arrangement of their contents constitute intellectual creations, are protected as such. This protection does not extend to the data or the material itself and is without prejudice to any copyright subsisting in the data or material contained in the compilation".

Consequently, the EU must grant copyright to databases that achieve a certain minimum level of creativity. This obligation is reflected in EU legislation.

3.2.2 Database protection in the EU

The main piece of relevant legislature in the EU is Directive 96/9/EC of the European Parliament and of the Council of 11 March 1996 on the legal protection of databases ("Database Directive").[78]

The Database Directive was not only a result of Member States each having their own regimes (which nevertheless fulfilled the requirements set forth in TRIPS, as seen above), it was also influenced by the lack of protection afforded to non-creative databases in the United States[79] as well as in the majority of EU Member States.[80]

Consequently, the Database Directive grants two types of protection depending on the type of effort that went into producing the database: copyright on the one hand and a *sui generis* right on the other.

This section will first consider the definition of the term database, then describe the two different types of protection afforded to databases in the EU and finally analyze the Database Directive as applied to EURECA.

3.2.2.1 Definition of "database"

Article 1(1) clarifies the scope of the Database Directive by stating that it *"concerns the legal protection of databases in any form"* and thus applies equally to electronic and non-electronic databases.

The Database Directive defines a database very broadly as *"a collection of independent works, data or other materials arranged in a systematic or methodical way and individually accessible by electronic or other means."*[81]

While computer programs used to make or operate databases accessible by electronic means are specifically exempt from protection under the Database Directive,[82] some

[78] Available online: http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:31996L0009.

[79] See Bainbridge, *Introduction to Information Technology Law*, p. 74.

[80] See Estelle Derclaye, *The Legal Protection of Databases*, p. 45 (2008).

[81] Article 1(2) Database Directive.

commentators argue that computer programs used to consult the database, but which are not necessary for its making or operation, should qualify on grounds that they would be analogous to a book's index.[83]

"Works" is meant in the traditional copyright sense and refers to literary, artistic and other such works. "Data" refers to "information", i.e. data understandable to humans, as contrasted to pure data, i.e. data which is independent of meaning and has not yet reached the status of human intelligible information.[84]

What the term "other materials" refers to is unclear. Some commentators argue that it is meant to include physical objects, so that a collection of stamps could achieve protection under the Database Directive, while others argue that nowhere does the Database Directive list any examples of physical objects, but only intangible ones, so that "other materials" must be interpreted in the same vein.[85]

Various national courts have made use of the broad definition and, in different decisions, granted database protection to:

"telephone directories, collections of legal materials, real estate information websites, radio and television guides, bibliographies, encyclopedias, address lists, company registries, exhibition catalogues, tourism websites, collections of hyperlinks, and hit parades."[86]

In considering the database definition, the European Court of Justice affirmed the broad scope of the Database Directive's wording and explained that a database is

"any collection of works, data or other materials, separable from one another without the value of their contents being affected, including a method or system of some sort for the retrieval of each of its constituent materials."[87]

However, the Court placed great emphasis on the requirement that the materials collected are "independent", i.e. *"separable from one another without their informative, literary, artistic, musical or other value being affected."*[88]

---

[82] See Article 1(3) Database Directive.

[83] See Estelle Derclaye, *The Legal Protection of Databases*, p. 69 (2008).

[84] Ibid, p. 58 et seq. (2008).

[85] Ibid, p. 59 et seq. (2008).

[86] Paul Goldstein and P. Bernt Hugenholtz, *International Copyright: Principles, Law, and Practice* (Oxford: Oxford University Press, 2012), p. 242.

[87] See Case C-444/02 *Fixtures Marketing Ltd v Organismos prognostikon agonon podosfairou AE (OPAP)*, para 32.

[88] Ibid, para 29.

Consequently, there are few restrictions to what collection of information actually constitutes a database. In particular, data need not be organized with the primary purpose of creating a database. It is sufficient that the data is organized and individually accessible and separable, even if the creation of the database was incidental to the actual purpose of, for example, accomplishing a certain result with the individual data.[89]

It has been argued[90] that the broad definition awarded to databases is at odds with the Database Directive's purpose of encouraging investments in information storage and processing systems to develop the information market within the EU,[91] because even biographies might be considered databases under the Database Directive.[92]

This view seems to forget the requirement that individual data be separable from the whole without impacting their individual value – a quite powerful restrictor. For example, while a biography can indeed be seen as a collection of individually accessible data (looking either at words or chapters), individual words cannot be separated without substantially losing their value, and individual chapters probably only in exceptional circumstances. Consequently, classifying a biography as a database seems a stretch.[93]

Finally, while the definition of database is broad, the Database Directive does not automatically award protection to all databases simply because they are databases. Only databases that fulfill certain requirements as to the effort that went into producing the database qualify for protection.

The Database Directive provides for two types of protection: copyright on the one hand and a *sui generis* right on the other.

3.2.2.2 Protection of databases under copyright

3.2.2.2.1 *Object of protection*

The Database Directive grants the author of a database a copyright in recognition of his "intellectual effort" in creating the database, as expressed through the selection or arrangement of the contents.[94] Such databases are called original databases[95] due to

[89] See Davison, p. 70 et seq.

[90] See Davison, p. 71 et seq.

[91] See Recital 7 et seqq. of the Database Directive

[92] See Davison, p. 72.

[93] See also Estelle Derclaye, *The Legal Protection of Databases*, p. 62 et seq. (2008).

[94] See Article 3(1) Database Directive.

[95] See European Commission, DG Internal Market and Services Working Paper – First evaluation of Directive 96/9/EC on the legal protection of databases, 2005, p. 3, available at:

http://ec.europa.eu/internal_market/copyright/docs/databases/evaluation_report_en.pdf.

the level of originality in creating the database that is required to qualify for copyright protection.

It is important to distinguish between the database structure and the contents of the database. The contents of the database are not subject to copyright protection through the Database Directive; on the contrary, the contents retain any and all rights they had prior to being entered into the database.[96] Copyright under the Database Directive only protects the database itself as the intellectual selection and arrangement of its contents, i.e. its structure.[97]

The intellectual effort requirement is meant to exclude non-original databases that are simple compilations,[98] i.e. created using purely non-intellectual, "sweat of the brow"-type efforts of time or money.[99]

The distinguishing factor in evaluating the level of originality is whether the author expressed his creative ability in an original manner by making free and creative choices, thereby stamping the database with his personal touch.[100]

If technical considerations or other constraints mean that creative freedom in the arrangement of the data cannot be exercised, originality in the sense of the Database Directive must be denied.[101] Intellectual effort as expressed through considerable skill and knowledge alone is insufficient for achieving copyright protection.[102]

3.2.2.2.2 *Scope of protection and exceptions*

By virtue of the copyright, the author of an original database enjoys an exclusive right to its use in a number of ways, including

"(a) temporary or permanent reproduction by any means and in any form, in whole or in part;

(b) translation, adaptation, arrangement and any other alteration;

---

[96] See Article 3(2) Database Directive.

[97] See Recitals 15 and 27 Database Directive.

[98] See Recitals 17 and 19 Database Directive.

[99] See European Commission, DG Internal Market and Services Working Paper – First evaluation of Directive 96/9/EC on the legal protection of databases, 2005, p. 3 et seq., available at:

http://ec.europa.eu/internal_market/copyright/docs/databases/evaluation_report_en.pdf.

[100] See Case C-604/10 *Football Dataco Ltd. and Others v Yahoo! UK Ltd. and Others*, para 38.

[101] See Case C-604/10 *Football Dataco Ltd. and Others v Yahoo! UK Ltd. and Others*, para 39.

[102] See Case C-604/10 *Football Dataco Ltd. and Others v Yahoo! UK Ltd. and Others*, para 42.

(c) any form of distribution to the public of the database or of copies thereof (...);

(d) any communication, display or performance to the public;

(e) any reproduction, distribution, communication, display or performance to the public of the results of the acts referred to in (b)".[103]

The Database Directive gives Member States the option of providing for exceptions in certain cases, such as extraction (not reutilization[104]) "for the *sole purpose* of illustration for teaching or *scientific research*, as long as the source is indicated and to the extent justified by the *non-commercial* purpose to be achieved"[105]. The research exception is understood to also exclude research that only has indirect commercial benefits. As a result, private companies are never able to avail themselves of the research exception.[106]

3.2.2.2.3 *Term of protection*

The term of protection is not explicitly stated in the Database Directive, but is derived from Directive 2006/116/EC of the European Parliament and of the Council of 12 December 2006 on the term of protection of copyright and certain related rights[107] and is 70 years following the database's creation.

3.2.2.2.4 *Authors of databases*

The author of a database is seen as the natural person who created the database and can be either an individual or a group of persons who then own the rights jointly.[108] If Member State legislation so permits, the author can also be the legal person designated as a right holder.[109] In cases where national legislation recognizes collective works, the economic rights are given to the person holding the copyright.[110]

---

[103] See Article 5 Database Directive.

[104] See Recital 50 et seq. Database Directive. But cf. Estelle Derclaye, *The Legal Protection of Databases*, p. 133 (2008), who argues that because copyright law in Europe without exception allows also reutilization for non-commercial research, and the rationale to protect and promote creativity and investment is similar, the Database Directive should also be interpreted to permit reutilization in such cases.

[105] Article 6(2)(b) Database Convention, which lists further exceptions that Member States may legislate. Emphasis added.

[106] See Estelle Derclaye, *The Legal Protection of Databases*, p. 133 (2008).

[107] As amended by Directive 2011/77/EU of the European Parliament and of the Council of 27 September 2011 amending Directive 2006/116/EC on the term of protection of copyright and certain related rights.

[108] See Article 4(1) and 4(3) Database Directive.

[109] See Article 4(1) Database Directive.

[110] See Article 4(2) Database Directive.

3.2.2.3 Protection of databases under the *sui generis* right

3.2.2.3.1 *Object of protection*

Because copyright protection afforded under the Database Directive is only for original databases, non-original databases are given their own *sui generis* right of protection for the *"blood, sweat and tears that go into producing a database"*[111].

Consequently, the Database Directive demands that *"there has been qualitatively and/or quantitatively a substantial investment in either the obtaining, verification or presentation of the contents"*[112]. The type of investment required can be time, financial resources, personnel, or technical means invested, or indeed any other "sweat of the brow"-type resource, as distinct from creative, intellectual efforts.

The ECJ is very strict in its understanding that the investment must be made to *obtain* the contents. A database that is a mere spinoff/by-product from another investment/activity (such as scientific data resulting from research) does not typically qualify for protection under the Database Directive's *sui generis* regime. There must additionally be a further substantial investment in obtaining, verifying or presenting the data.[113]

In other words, the ECJ demands that the investment be made specifically to *"seek out existing independent materials and collect them in the database"*.[114] An investment in *"the creation of materials which make up the contents of a database"*[115] is deemed insufficient. As a result, creators of data rarely enjoy a sui generis right of protection for any non-original database constructed out of that data – so-called "single source databases"[116] – unless there is also a substantial investment in the verification or presentation of the contents.

Such an additional substantial investment is often the case for data resulting from clinical trials. Such data must first undergo an extensive verification process before it can be used in research and entered into a database. Importantly, the data verification

---

[111] Jasper A. Bovenberg, *Property Rights in Blood, Genes & Data: Naturally Yours?*, p. 159 (2006).

[112] Article 7(1) Database Directive.

[113] See Estelle Derclaye, *The Legal Protection of Databases*, pp. 92 et seqq. (2008).

[114] Case C-203/02 *The British Horseracing Board Ltd and Others v William Hill Organization Ltd*., para 42.

[115] Case C-203/02 *The British Horseracing Board Ltd and Others v William Hill Organization Ltd*., para 42. See also Jasper A. Bovenberg, *Property Rights in Blood, Genes & Data: Naturally Yours?* p. 176 et seq. (2006).

[116] See European Commission, DG Internal Market and Services Working Paper – First evaluation of Directive 96/9/EC on the legal protection of databases, 2005, p. 14, available at:

http://ec.europa.eu/internal_market/copyright/docs/databases/evaluation_report_en.pdf.

process is subsequent and separate from the obtaining/creation of the original data, as otherwise it would be excluded from protection.

"*Verification*" is understood to mean steps taken to ensure the information is reliable. As with the requirement of "obtaining" data, an investment in verifying information during the information's creation is excluded.[117]

"*Presentation*" is defined as the way data is structured and made accessible to others, so that the creation of an index or the design of a user interface can all be seen to fulfill the requirements of an investment in the presentation of the contents.[118]

Finally, the investment must also be of a "*qualitatively and/or quantitatively*" substantial nature.[119] The Database Directive does not define "*substantial*" and neither has the ECJ ruled on the matter. However, the Preamble of the Directive indicates that, "*as a rule, the compilation of several recordings of musical performances on a CD (...) does not represent a substantial enough investment to be eligible under the sui generis right*".[120] Member States generally adopt a low level approach to the requirement, and the Advocate General has taken the same stance.[121]

As regards the quantitative and/or qualitative qualification, these are understood to mean investments quantifiable and not-quantifiable, respectively, such as money on the one hand and intellectual effort on the other.[122]

3.2.2.3.2 *Scope of protection and exceptions*

The protection extends against unauthorized extraction and re-utilization of a substantial part, evaluated qualitatively and/or quantitatively, of the contents of the database,[123] or the repeated and systematic use of insubstantial parts that infringes upon the legitimate interests of the database maker.[124]

---

[117] See Estelle Derclaye, *The Legal Protection of Databases*, p. 97 (2008).

[118] See Estelle Derclaye, *The Legal Protection of Databases*, p. 97 et seq. (2008).

[119] Article 7(1) Database Directive.

[120] Recital 19 Database Directive.

[121] See Estelle Derclaye, *The Legal Protection of Databases*, pp. 75 et seqq. (2008).

[122] See Case C-338/02 *Fixtures Marketing Ltd v Svenska Spel AB*, para 28.

[123] See Article 7(1) Database Directive.

[124] See Article 7(5) Database Directive.

The ECJ has held that a substantial part, evaluated quantitatively, refers to the volume of data in relation to the database as a whole.[125] Evaluated qualitatively, a substantial part refers to the scale of investment in obtaining the contents.[126]

"Extraction" is defined as "*the permanent or temporary transfer (…) to another medium by any means or in any form*".[127] Extraction does not require physical copying of contents, and neither does it require the intention of creating a competing product.[128] For example, consulting a protected database, assessing its contents individually and then using it for the creation of a new database that expands upon the contents of the first database can constitute extraction. Specifically, the ECJ held that consulting a database of poetry titles in order to create a database of poems can constitute extraction.[129]

"Re-utilization" is defined as *"any form of making available to the public (…) by the distribution of copies, by renting, by on-line or other forms of transmission"*, albeit subject to the principle of exhaustion.[130]

As regards the above mentioned repeated and systematic extraction/reutilization of insubstantial parts, the ECJ has held that such use is prohibited, *"the cumulative effect of which would be to seriously prejudice the investment made by the maker of the database just as the extractions and/or re-utilisations*"[131] – which is the case where either the database as a whole or in substantial parts is basically reconstituted by the systematic and repeated efforts of the user.[132]

In parallel to the copyright regime, protection is granted without prejudice to any rights residing in the contents themselves,[133] but with certain exceptions possible, such as for scientific research.[134] The details are the same as *supra*.[135]

---

[125] See Case C-203/02 *The British Horseracing Board Ltd and Others v William Hill Organization Ltd*., para 70.

[126] See Case C-203/02 *The British Horseracing Board Ltd and Others v William Hill Organization Ltd*., para 71.

[127] Art. 7(2)(a) Database Directive.

[128] See Diane Rowland, Uta Kohl and Andrew Charlesworth, *Information Technology Law*, p. 390 et seq. (4th ed, 2012).

[129] See Case C-304/07 *Directmedia Publishing GmbH v Albert-Ludwigs-Universität Freiburg*, paras 9 et seqq.

[130] See Article 7(2)(b) Database Directive.

[131] Case C-203/02 *The British Horseracing Board Ltd and Others v William Hill Organization Ltd*., para 86.

[132] See Case C-203/02 *The British Horseracing Board Ltd and Others v William Hill Organization Ltd*., para 87.

[133] See Article 7(4) Database Directive.

3.2.2.3.3 *Term and beneficiaries of protection*

The *sui generis* right begins upon completion or being made publically available of the database and runs for 15 years from the first of January of the year following completion; any substantial change or accumulated changes to the database that require a substantial new investment renew the term.[136] There is no limit to the number of renewals possible, so that databases that require ongoing and substantial updating are effectively protected for as long as they are kept alive.

The *sui generis* right is extended to natural persons who are makers of or right holders to databases and are nationals or habitual residents of a Member State. Legal persons must be formed according to the laws of a Member State and also have their registered office, central administration or principal place of business within and a genuine link to the economy of a Member State. [137]

The maker of a database is seen as "*the person who takes the initiative and the risk of investing*"[138], but excluding subcontractors.

This definition means that databases made by the State arguably fall outside the scope of *sui generis* protection. Because taxpayer's money is used, the State does not undertake a financial risk when making databases[139] and is therefore not the maker of a database according to the Database Directive. Nevertheless, national courts have granted State-made databases protection, albeit before ECJ decisions on the requirement of truly "obtaining" data.[140]

3.2.3 Conclusions for EURECA

Mapping to the EHR and CT systems is envisaged by the Project. This endeavor will be facilitated by the development environment which will bridge the EHR and CT systems via the semantic core data sets. The semantic core data sets will be bridged to the EHR and CT systems via canonical information models on the basis of specified parameters. The concepts of the core data sets will be either extracted or mapped with the concepts from existing standardized terminologies, as supplemented with the unique identifiers, well understood meaning and a set of synonyms they can be

---

[134] See Article 9 Database Directive.

[135] See *supra*, section 3.2.2.2.

[136] See Article 10 Database Directive.

[137] See Article 11(1) and 11(2) Database Directive.

[138] See Recital 41 Database Directive.

[139] See Estelle Derclaye, *The Legal Protection of Databases*, p. 74 (2008).

[140] See Estelle Derclaye, *The Legal Protection of Databases*, p. 74 (2008).

referred as[141]. Access to the schema and instance level datasets will be provided by development environment (e.g. “surrogate databases”)[142].

“*The semantic core dataset is an essential prerequisite to semantically aware access to both EHR and clinical trial data in a machine processable manner*”[143]. Against this background it may be concluded that: (a) medical concepts will be assembled into a semantic core data set as individual items and due to a unique identifier each concept can be individually accessible; (b) the concepts will be accessed in a machine processable manner, as facilitated by the technical environment; (c) the concepts will be arranged on the basis of certain parameters in a way so that bridging with the information models of EHR and CT may take place. Qualified as a collection of individual medical concepts, arranged in a systematic way so that each concept can be individually accessible via electronic means, a semantic core dataset can be considered as object of legal protection of databases in the meaning of Article 1 Database Directive.

The concepts of the core data sets will be extracted or mapped with the concepts of standardized medical ontologies, such as: SNOMED CT, Semantic Health and will be validated in concrete use cases[144]. The EURECA environment will operate and the data will be processed and represented through a number of ICT tools, applications and services, developed for specific data procession tasks[145]. Prior to entering and being processed in EURECA, the medical concepts will go through extensive evaluation and validation[146]. It follows that: the concepts of the core dataset will be gathered from multiple sources, will go through the validation phase and will be represented and made accessible by machine processable means.

Both collection, validation and representation of the concepts, as processed in a core dataset, requires deployment of financial, technical and professional human resources.

Investments deployed in extracting and collecting concepts, relevant for EURECA from existing terminologies in the medical domain, costs for procession and representation of data by software and expenses on procurement of software, server and hardware, efforts and expenditures for maintaining and actualization of the concepts and associated expenses on human resources and expert knowledge for verification of the concepts shall prove that economic risk for collecting, verifying and presentation of

[142] DoW, Part A, WP 9, T. 9.1, p.35.

[143] DoW, Part B, WP 4, p. 74.

[144] DoW, Part B, WP 4, p. 74.

[145] DoW, Part A, WP 6, p. 25.

[146] DoW, Part A, WP 9, T. 9.4, p. 36.

medical data to be sufficient to qualify the semantic core dataset as protected by sui generic database right in the meaning of Article 7 Database Directive[147].

Nevertheless, the technological infrastructure and data processing means, used to operate the dataset, are excluded from protection by the sui generis database right[148]. These means may deserve protection as protectable subject under Software Directive on their own. The same relates to the medical concepts, which per se may be eligible for protection by copyright or other rights, irrespective of the database right in the core dataset[149].

As regards protection of the semantic core data set by copyright, so the efforts, labor and financial expenses and expert knowledge born for constructing the dataset are irrelevant for the copyright protection[150]. It is only through the conceptual creative performance represented by selection and arrangement of data, that copyright protection may be justified[151]. By analysis of the EURECA materials at hand, the intellectual creative performance in how the concepts are selected and arranged has not been identified. Thus, the legal basis to consider the semantic core data set as eligible for copyright protection is deemed insufficient.

3.2.4 Legal analysis of using external data sources in EURECA

3.2.4.1 Use of external data sources in EURECA[152]

For developing the semantic interoperability layer and semantic dataset in EURECA a number of standardised and widely used medical ontologies are assessed and considered for use[153]. Inter alia the following medical vocabularies are indicated: MedDRA[154], SNOMED CT[155], MeSH[156], LOINC[157], WHO classifications: ICD -10[158] and ICD-O[159].

---

[147] Wiebe A., Der Schutz der Datenbanken – ungeliebtes Stiefkind des Immaterialgüterrechts/Protection of databases – an unbeloved stepchild of Intellectual Property Law, CR, 1/2014, p.1.

[148] Recital 23 Database Directive.

[149] Article 7 Paragraph 4 Database Directive.

[150] Wiebe, supra, p. 4.

[151] Ibid.

[152] According to DoW, Part A and Part B.

[153] DoW, Part B, p.29.

[154] The ICH Steering Committee (SC), Medical Dictionary for Regulatory Activities (MedDRA), available at: http://www.meddra.org/

[155] IHTSDO, SNOMED CT, available at: http://www.ihtsdo.org/snomed-ct/

Data from external data sources are going to be used in EURECA as follows. Medical terms, relevant for EURECA, will be either extracted into or mapped with the concepts of semantic core dataset[160]. In particular, the re-use may take place via: *"...using those subsets that are relevant for the task at hand"*[161]. Also, concepts from existing terminologies, inter alia: SNOMED CT, ICD, ICD-10 will be mapped with semantic data set in EURECA[162]. An approach to make external data sources, relevant for EURECA, available to the platform will be developed[163]. For instance, databases from the bioinformatics field, drug related databases and data sources on cell lines are considered for making available to EURECA platform[164].

Operation of the semantic core data set and its sources will be facilitated by the technical infrastructure. Access to the various technical implementations of the sources will be supported by the uniform interface of the canonical model[165]. The web platform will be created for EURECA, among exploitation options free access for EURECA partners and paying for outsiders are considered[166].

The two major issues to consider when external data sources are used are: copyright related issues and issues related to use of sources protected by sui generis database right.

3.2.4.2 Copyright and licensing issues

External data sources may be subject to third parties rights and be protected by EU and/or non-EU copyright laws. For example, the ontologies MeSH, MedDRA, LOINC are subject to the jurisdiction of U.S. law, SNOMED CT is EU based. The ontologies and data sets contained therein are, as a rule, provided for use under permission of the right holders and are included under specific terms of use. Such acts, as:

---

[156] U.S National Library of Medicine, Medical Subject Headings, MeSH, available at: http://www.nlm.nih.gov/mesh/MBrowser.html

[157] Regenstrief Institute, Inc and the LOINC Committee, LOINC, available at: http://loinc.org/

[158] WHO, International Classification of Diseases (ICD), available at: http://www.who.int/classifications/icd/en/

[159] WHO, International Classification of Diseases for Oncology, 3rd Edition (ICD-O-3), available at: http://www.who.int/classifications/icd/adaptations/oncology/en/

[160] DoW, Part A, WP 10, p. 39.

[161] DoW, Part B, p.28.

[162] DoW, Part A,WP 4, p. 19.

[163] DoW, Part B, p.39.

[164] Ibid.

[165] DoW, Part A, WP 9, T. 9.3, p.35.

[166] DoW, Part A, WP 10, p. 39.

transmission, reproduction, modification, translation, creation of derivatives and making available to the public of copyright protected works are subject to authorisation requirement and, if unauthorised, may be prohibited by the right holder.

Most of the mentioned sources, in particular, ICD-10, SNOMED CT, MedDRA, LOINC are included into the source vocabularies of the UMLS Metathesaurus. In Article 4.1.5 CA the Parties agreed that they may use one or more source vocabularies, covered by the UMLS Metathesaurus License[167] (UMLS License), to develop the Foreground and to grant Access Rights to such Foreground, subject to the terms of the UMLS License.

Based on this, the presumption is that Parties which use the named data sources during their work in EURECA shall have the UMLS License.

The UMLS License is free of charge, non-transferrable and non-exclusive[168]. It allows subject to the license terms to use the UMLS Metathesaurus, along with its sources and terminology services, to incorporate its content in any computer applications or systems, which will provide access to biomedical information[169] and to distribute its contents as an integral part of such computer applications or systems, provided, they do not serve the redistribution of vocabulary sources only[170]. It also allows to download data files, including its knowledge sources and SNOMED CT[171]. By this it requires that NLM or right holders of the vocabulary sources be acknowledged and use of material from copyrightable sources be accompanied with copyright notice, stated in Section 11 UMLS License. Any alteration of the UMLS content or vocabulary source contents is prohibited, but such contents may be used and included “verbatim” with appropriate labelling together with external sources in applications, which the Licensee may create[172].

It means, the Parties may use, download and incorporate contents from UMLS or its sources, into the computer applications or systems they create, and distribute such systems, subject, however, they comply with the UMLS Licence terms or license terms of other sources, included into UMLS Metathesaurus.

Although, the UMLS License extends to and allows use vocabulary sources it includes, under the umbrella of UMLS License (as the case with use of SNOMED CT may be), however, along with that, it explicitly says that for use of some sources additional restrictions may apply. By this, it is preserved, that use of source vocabularies, downloaded from UMLS, may be used under the terms of the separate agreement.

---

[167] NLM, License Agreement for Use of the UMLS® Metathesaurus®, available at: https://uts.nlm.nih.gov/help/license/LicenseAgreement.pdf.

[168] Section 1, 2 UMLS License.

[169] Section 1 UMLS License.

[170] Section 3 UMLS License.

[171] NLM, UMLS Terminology Services, available at: https://uts.nlm.nih.gov/home.html.

[172] Section 11 b) UMLS License.

For using source vocabularies beyond the scope as allowed under the UMLS license agreement, the licensees are advised to contact the respective right holders and negotiate a separate license[173].

For instance, use of ICD -10 is allowed under the UMLS License but subject to reservation that ICD-10 contents may be used in internal use of the Licensee only. It includes internal research and product development, but ICD materials may not be incorporated into any publicly available computer based systems or bulletins, including the Internet, translation, creation of derivative works, making ICD materials available to the public and use on commercial scale are excluded[174].
The same relates to the use of LOINC, which may be used under the UMLS Licence, as long as the scope of use is covered by its terms. Use of LOINC, as downloaded from the UMLS, is explicitly subject the LOINC License terms[175].

Also use of MedDRA, covered by the UMLS License, is subject to the restricted use for internal research and product development, excluding using and incorporating the MedDRA contents in publicly accessible computer systems, as the case envisaged by EURECA may be.

Use of SNOMED CT, which is considered to form a primary source for the semantic data set in EURECA, is allowed for use under the UMLS License, but explicitly subject to the licence terms of the SNOMED CT Affiliate License Agreement, which is separately included into Appendix 2 of UMLS License.

For advising, in how far the Parties´ use of external sources in EURECA is covered by the UMLS License, the practical background shall be analysed against the UMLS License terms. The manner how external data items are used (e.g. copying, mapping, incorporation into or access by information systems with the perspective of making these available to the public, etc.), in what scope external data sets are used (e.g. volume of data used) and terms, under which external data sources are provided for use (e.g. associated copyright and licensing policy) shall be analysed on a case by case basis. The Parties, working with external data sources in EURECA, are expected to hold the UMLS Licence, be aware with the UMLS license terms and license terms of vocabulary sources, which they are using, and to comply with the terms of use. With respect to use of external data sources it is advised to check in how far the scope of use of external data sources in EURECA is covered by the UMLS License. Shall the scope of use (or perspective scope of use individual services) go beyond the scope of UMLS License, a legal advice would be to contact the respective right holder and obtain the appropriate license, as shall apply. Below we provide some legal guidance in what scope some the external data sources, interesting for EURECA, may be used and what conditions apply.

[173] Section 12 UMLS Lisence.

[174] Section 12.3 Categpry 3 UMLS.

[175] LNC246, Appendix 1 UMLS Licence.

3.2.4.2.1 *MeSH terms of use*

The source vocabulary MeSH is included into UMLS and its use is covered by the UMLS License, so that no additional restrictions apply.

By download and use of data from MeSH the terms of NLM licensing policy apply[176]. The NLM record (or portion thereof) in the product/service must be labeled and NLM must be identified as the source, the downloaded items must be adjusted to corrections made by NLM on annual basis, description how the product/service was derived must be provided to the users, etc[177].

For copyright policy and terms of use MeSH please see: https://www.nlm.nih.gov/databases/download.html.

3.2.4.2.2 *MedDRA terms of use*

MedDRA is also covered by UMLS License and may be used, but the extent of use is subject to certain restrictions.

MedDRA is maintained by ICH and is compatible with WHO databases and is subject to ICH licensing policy. The ICH copyright in such information must be acknowledged, changes, if any, identified, impression that any adaptations or modifications are endorsed by ICH must be avoided.

Use and reproduction of data items, provided Use of MedDRA is limited to internal research and product development. Incorporation of material from MedDRA in any publicly accessible computer-based information system, or public electronic bulletin board including the Internet; publishing or translating or creating derivative works; selling, leasing, licensing, or otherwise making available to any unauthorized party; and copying for any purpose except for back up or archival purposes requires additional license. Use, incorporation into other works, adaptation, modification, translation and distribution to the public of material contained in MedDRA is allowed on the following conditions: with copyright policy of third parties, require authorisation of the right holder[178].

MedDRA may be used under UMLS License for research and non-commercial purposes or by any non-commercial institutions conducting non-commercial work. If MedDRA is required to be used in or for development of software products, the license for software development might be needed. This license is limited to software development and testing with MedDRA, but excludes support services (e.g., coding, analysis, transmission of MedDRA coded data).

---

[176] NLM, Copyright Information & Downloading National Library of Medicine Data, available at: https://www.nlm.nih.gov/databases/download.html

[177] NLM, Copyright Information & Downloading National Library of Medicine Data, available at: https://www.nlm.nih.gov/databases/download.html

[178] ICH, Legal Notice, available at: http://www.meddra.org/legal-mentions

For licensing policy of MedDRA please see:
http://www.meddra.org/subscription/subscription-type.

3.2.4.2.3 *LOINC terms of use*

Logical Observation Identifiers Names and Codes (LOINC®) is covered by UMLS License to the extent, as not limited by the LOINC license.

LOINC and rights in it are held by Regenstrief Institute, Inc. It is provided for use by permission of the right holder and under special terms of use[179].

Perpetual worldwide royalty free permission to use, copy or distribute the licensed materials is granted. Relevant for EURECA is that use, copying, modification to the extent of normal use and distribution as licenses materials as well as incorporation as such into other master dictionaries and distribution of these together is allowed upon condition that LOINC materials are properly labelled, terms of use are observed and copyright and license notices are attached and made clear to the users[180]. Modification, translation and creation of derivative works from LOINC materials is expressly excluded and is explicitly subject to written permission of the right holder, i.e. Regenstrief Institute, Inc. Translation of LOINC materials into any other language also falls under creation of derivatives. Intended translations shall be notified to and rights in such translations pass to Regenstrief Institute, Inc. along with translated versions. Translations may be licensed under the same license terms as apply to LOINC[181].

The use of codes, included into LOINC under copyright policy of third parties, is also subject to the conditions that copyright and license notices must be retained. As a minimum use of third party items for clinical, research and non-commercial purposes, as well as in commercial software and clinical database systems are allowed.

For further details on licensing policy and terms of use LOINC please see: http://loinc.org/downloads/files/LOINCManual.pdf or contact Regenstrief Institute, Inc. at loinc@regenstrief.org.

3.2.4.2.4 *ICD terms of use*

ICD-10 is included into UMLS and covered by UMLS License, ICD-O – not. Use of ICD-10, as allowed under UMLS License, is limited and subject to the internal research and internal product development. Beyond that, scope of use is subject to WHO licensing.

Use of ICD-10 and ICD-O for commercial or non-commercial research purposes are allowed, however, license for commercial use or license for non-commercial research, depending on the EURECA exploitation options, must be obtained.

---

[179] Regenstrief Institute, Inc., LOINC and RELMA Terms of Use, available at: http://loinc.org/downloads/files/LOINCManual.pdf

[180] Section 10 LOINC and RELMA Terms of Use.

[181] Section 12 LOINC and RELMA Terms of Use.

Commercial license will allow to incorporate and distribute WHO classifications in software products for sale, but will not extend to creation of modifications and/or derivatives. For obtaining commercial license, which might be relevant to EURECA commercial exploitation options, an application form available at: http://www.who.int/about/licensing/classifications/en/ must be completed and submitted to WHO.

For further details on licensing and terms of use ICD please see: http://www.who.int/about/licensing/classifications/en/.

3.2.4.3 Legal issues related to sui generis database right

External data sources which are EU-based and qualify as databases in the meaning of Article 7 of the Database Directive, may be protected under the *sui generis* data base right. Re-use of contents from such databases in whole or substantial part can be considered as acts which require authorisation of the right holder[182]. Use of insubstantial parts may be allowed for public databases[183] as long as such acts do not *"conflict with normal exploitation of the database or unreasonably prejudice the legitimate interests of the maker of the database"*[184].

For legal reasoning on the terms *"extraction"* and "*re-utilisation"* and what volumes of data constitute *"substantial parts... evaluated qualitatively and/or quantitatively"* and in what scope extraction and/or re-utilisation of "*insubstantial parts*" from the database contents are allowed please see Part 3.2 on Database Protection.

The ECJ in its case law tends to interpret the terms *"extraction*" and "*re-utilisation"* rather broadly[185]. Making contents of the database accessible to the public "*by any means or in any form"*, including "*on-line or other forms of transmission"*[186] are considered as extraction or re-utilisation of the database contents in the meaning of Article 7 Paragraph 2 Database Directive. Such acts must as such, if substantial parts or whole contents of the database are concerned, be authorised by the right-holder.

This broad interpretation may relate to any acts which make results of a database publicly available in a manner by which the maker of the database is deprived of the possibility to recoup his investments; "*re-utilization*" relates to any unauthorised action aimed to distribute contents of the protected database[187]. Hereby, making datasets of

[182] Article 7 Paragraph 2 Database Directive.

[183] Article 8 Paragraph 1 Database Directive.

[184] Article 8 Paragraph 2 Database Directive.

[185] ECJ, Case C-203/02, The British Horseracing Board Ltd and Others v William Hill Organization Ltd., Paragraph 51; ECJ, Case C-173/11 of 18.10.2012; Rammos T., EuGH: Weiterverwendung wesentlicher Teile einer Datenbank/ ECJ: Re-utulisation of substantial parts of a database, CR 3/2014, p. 158, Paragraph 34.

[186] Article 7 Paragraph 2b) Database Directive.

[187] Rammos T., EuGH: Weiterverwendung wesentlicher Teile einer Datenbank/ ECJ: Re-utulisation of substantial parts of a database, CR 3/2014, p. 158, paragraph 36; ECJ, Judgment

a protected database accessible to the users via a specialised web search engine, tailored to provide, in essence, the same options as the protected database, has been recognised as re-utilisation of the whole or substantial parts of the database in the meaning of Article 7 Database Directive.

The ECJ recognized that:

> *"...an operator who makes available on the Internet a dedicated meta search engine... which offers the same range of functionality... 'translates' queries from end users into the search engine for the database site 'in real time' ...and presents the results to the end user using the format of its website... comparable to those used by the search engine of the database site concerned..."*

re-utilizes all or a substantial part of the contents of a database protected under Article 7 of the Database Directive[188].

Provided the same or similar approach is envisaged by EURECA, this qualification and legal conclusion may be relevant for EURECA as well. In particular it may prove to be valid when substantial parts of external data sources are concerned. In particular, use of SNOMED CT deserves particular attention, since namely re-use of this data source in "*substantial part"* of its contents is envisaged.

The clinical healthcare terminology SNOMED Clinical Terminology (SNOMED CT)[189] is indicated as the primary source of medical terms of relevance for EURECA and extraction or mapping the medical terms of SNOMED CT with the concepts of EURECA data set are envisaged.[190] By this, substantial parts of SNOMED CT contents may be concerned. Making substantial part of SNOMED CT contents available to the public via the web platform of EURECA may be considered as re-utilization of substantial part of contents of a protected database - an action for which authorization of the right holder is required[191].

3.2.4.4 Use of SNOMED CT

SNOMED CT is "*the most comprehensive, multilingual clinical healthcare terminology in the world"*[192]*.* It is developed and maintained by the International Health Terminology Standards Development Organisation (IHTSDO). All IPR in SNOMED CT, such as

---

of 19.12.2013, Case C-202/12, Innoweb BV v Wegener ICT Media BV, Wegener Mediaventions BV.

[188] ECJ, Judgment of 19.12.2013, Case C-202/12, Innoweb BV v Wegener ICT Media BV, Wegener Mediaventions BV.

[189] The International Health Terminology Standards Development Organisation (IHTSDO), SNOMED CT, available at: http://www.ihtsdo.org/snomed-ct/

[190] DoW, Part B, WP4, p. 74.

[191] Article 7 Paragraph 2 Database Directive.

[192] IHTSDO, SNOMED CT, available at: http://www.ihtsdo.org/snomed-ct/

rights in trademarks, database rights, copyrights in computer programs, know-how, etc. are preserved by the IHTSDO[193].

The SNOMED CT medical terms will be either extracted or mapped with the concepts of EURECA dataset in specific relationships. The concepts of EURECA dataset will be provided with additional properties, such as: identifiers, well understood meaning and synonyms[194]. Against this background, the contents of EURECA core dataset may be considered to comprise: SNOMED CT content (concepts, descriptions and relationships)[195], additional properties or information about such and/or any set of relationships between the content of SNOMED CT and EURECA core dataset. The latter may comprise nomenclature, classification, knowledge structure, cross-mapping and sub-sets[196]. Having this quality, the EURECA core dataset is most likely to qualify as a SNOMED CT derivative in the meaning of SNOMED CT licence terms[197]. Creation and distribution of SNOMED CT derivatives is subject to the IHTSDO licensing and requires acceptance and compliance with the SNOMED CT® AFFILIATE LICENCE AGREEMENT (ALA)[198].

Apart from that, provision of "*web-based and other publicly available software or services that incorporate, or provide access to SNOMED CT®",* including browsers, software and services with programmatic access to SNOMED CT or its derivatives, is subject to the licensing policy of the IHTSDO too[199].

SNOMED CT is also included into the vocabulary sources of UMLS and use of SNOMED CT is covered by the UMLS License. Although SNOMED CT is included, however its use is explicitly subject to the terms of Affiliate License Agreement, as included into the UMLS License in Appendix 2 and which is binding on UMLS Licensees. Although there are no charges for using UMLS from NLM, however, there may be charges[200] associated with use of SNOMED CT[201]. Charges may apply in

---

[193] Clause 8 Affiliate License Agreement, available at: IHTSDO, SNOMED CT Licensing, http: http://ihtsdo.org/fileadmin/user_upload/Docs_01/License/Ihtsdo_AffiliateLicenceAgreement_v11.pdf

[194] DoW, Collaborative Project, Part B, p.74.

[195] Appendix A, ALA.

[196] Ibid.

[197] Appendix A, ALA.

[198] IHTSDO, Licensing, available at: http://www.ihtsdo.org/licensing/

[199] IHTSDO, Guidance on Provision of Publicly Available SNOMED CT Browsers and Related Services, available at: IHTSDO, Licensing: www.ihtsdo.org/browser_license_guidance.pdf

[200] IHTSDO, Affiliate License Fees, available at: http://www.ihtsdo.org/licensing/affiliatefees.

[201] NLM, How to License and Access the Unified Medical Language System® (UMLS®) Data, available at: http://www.nlm.nih.gov/databases/umls.html.

countries, which are not part of IHTSDO[202]. So that use of SNOMED CT in EURECA be done in a legally correct manner and with no charges for use in Non-Member countries of IHTSDO (e.g. Germany and Universität des Saarlandes) due, there is a legal option to recognise EURECA as "Qualifying Research Project" and apply for a fee waiver.

3.2.4.4.1 *SNOMED CT Affiliate License Agreement*

"The IHTSDO Affiliate License is a click-through license, which requires you to accept the conditions for use prior to accessing SNOMED CT. Most Member countries provide SNOMED CT free of charge to users, although some may charge a small fee for cost recovery"[203].

The IHTSDO grants a perpetual (until terminated), worldwide, non-exclusive, non-transferable licence[204] with a broad scope of rights. The scope of Affiliate License can be deemed as covering activities and services, which will be provided under the umbrella of EURECA, in full. Under an Affiliate License Agreement use of SNOMED CT for internal activities and research, creation of extensions and derivatives, incorporation of SNOMED CT into the products, created by the Licensee (i.e. EURECA or EURECA Party), and distribution of such products are allowed, as long as the SNOMED CT license terms are complied with[205].

Use of the International Release is governed by the Affiliate License Agreement, use of National Releases may be subject to the national licensing policies[206]. Relevant for EURECA is that translation of medical terms, extracted from SNOMED CT, into other languages, as envisaged by EURECA[207], must be consented by and agreed with the IHTSDO[208]. Also, any modifications to the SNOMED CT contents, except formatting[209], modification of documentation and associated software, except open source, are not allowed, unless agreed with the IHTSDO as well[210].

If the EURECA core dataset may implement or will be built on the basis of SNOMED CT specifications, including the internal logic, editorial policies, guidelines and

---

[202] IHTSDO, Members of IHTSDO, available at: http://www.ihtsdo.org/members/

[203] IHTSDO, Licensing, Licensing SNOMED CT for Use in a Member Country, available at: http://www.ihtsdo.org/licensing/

[204] Clause 2.1 ALA.

[205] Clause 2.1 ALA.

[206] Clause 2.3 ALA.

[207] DoW, Part B, p. 73.

[208] Clause 2.4 ALA.

[209] Clause 2.1.4 ALA.

[210] Clause 4.1, 4.2 ALA.

characteristics, published by the IHTSDO, then it may qualify as Standards-Based Derivative[211]. Creation of standards-based derivatives foresees as a pre-condition that a Namespace Identifier, designating the organisation, responsible for creating and maintaining such a derivative, must first be issued by the IHTSDO[212]. The Licensee has a right to request the IHTSDO to issue a namespace identifier for that derivative[213]. Hereby, by creation of SNOMED CT derivatives compliance with the IHTSDO standards and regulations must be observed[214].

Use of SNOMED CT in EURECA is connected to the use of semantic core dataset and will be facilitated by some software tools. Such software systems and tools may be deployed in a way as to analyse or create records using encoding of SNOMED CT or allow to search and display SNOMED CT components, including via programmatic access[215]. If such systems and tools are used the following must be observed. First, tools which would allow copying of the substantial parts of the SNOMED CT contents by the users are explicitly excluded[216]. Fees for access to such systems or tools may not be charged, except when the fees are incidental to the provision of licensing or consulting services[217]. Search engines or software with an accessible API that permits "*SNOMED CT terms or identifiers to be copied ... or extracted ... may be used in ways that are subject to charges in a Non-Member Territory*"[218] and reporting to the IHTSDO.

Although the Affiliate License is a worldwide license[219] and shall be sufficient to use SNOMED CT in all countries, however, using or providing access to SNOMED CT in Non-Member Territories[220] may be subject to charges, unless exceptions apply.

There are certain exceptions, elaborated by the IHTSDO for research and charitable use, which may apply to EURECA too. Research projects, which are recognised as

---

[211] Appendix A, ALA.

[212] Ibid.

[213] Clause 3.2 ALA.

[214] Clause 3.3 ALA.

[215] IHTSDO, Guidance on Provision of Publicly Available SNOMED CT Browsers and Related Services, available at: IHTSDO, Licensing: www.ihtsdo.org/browser_license_guidance.pdf

[216] Clause 2.2.4 ALA; Guidance on Provision of Publicly Available SNOMED CT Browsers and Related Services.

[217] Ibid.

[218] IHTSDO, Guidance on Provision of Publicly Available SNOMED CT Browsers and Related Services

[219] Clause 2.1 ALA.

[220] Appendix A ALA; IHTSDO, Members, available at: http://www.ihtsdo.org/members/

"Qualifying Research Projects" by the IHTSDO, are released from the fee payment obligation[221].

3.2.4.4.2 *Use of SNOMED CT for research in EURECA*

In order that SNOMED CT could be used free of charge by the Parties in EURECA, without restrictions to certain territories (IHTSDO Members),a legal option may be to present EURECA to the IHTSDO as a "Qualifying Research Project" in order to be recognised as such.

For this EURECA shall meet the following requirements:

- be supported by a formal proposal that has been peer reviewed;
- be ethically approved in accordance with national law;
- be conducted within a definite timeframe;
- have the research results offered for publication in peer-reviewed public journals and provided to the IHTSDO free of charge.[222.]

It is presumed that EURECA as an ICT Research Project shall satisfy these criteria in full.

To follow this option, for release of charges a fee waiver for EURECA shall be submitted to IHTSDO. For this, the IHTSDO advises that the authorised representative, responsible for the project (i.e. Project Coordinator, Philips Electronics Nederland BV, located in the Netherlands[223]) should sent the formal letter to the National Release Center[224]or the IHTSDO directly, if project is located outside the IHTSDO Members[225].The letter shall contain the "*project description, names of the project leader and any other stakeholders involved, project end date, expected outcomes*"[226].

This legal option is provided as legal indication and submitted for consideration at discretion of the Parties, who are more aware with the practical scenarios and exploitation options in place.

---

[221] IHTSDO, Licensing, Special Exemptions from Fees, available at: http://www.ihtsdo.org/licensing/

[222] Appendix A ALA.

[223] Part I CA.

[224] The National Release Center of Netherlands is: National IT Institute for Healthcare in the Netherands (Nictiz). Contact information can be found at: http://www.ihtsdo.org/members/nl00/.

[225] IHTSDO, Qualifying Research Project, available at: http://www.ihtsdo.org/licensing/affiliatefees/

[226] IHTSDO, Licensing, Qualifying Research Project, available at: http://www.ihtsdo.org/licensing/affiliatefees/

If individual Parties intend to provide services with the use of or access to SNOMED CT beyond the scope of EURECA, such Parties shall contact the National Release Center and follow the licensing procedure, as advised. It shall be noted, that use of SNOMED CT and provision of services which incorporate or provide access to SNOMED CT beyond the scope of Qualifying Research Project and not related to charitable or humanitarian causes in Non-Member Territories may be subject to charges[227]. For using SNOMED CT beyond EURECA or on individual basis and what charges may apply, we advise to consult the National Release Center, accordingly.

3.2.4.4.3 *Sub-Licensing SNOMED CT to the end users*

Services and tools, which EURECA will provide on the web platform, may include such which will incorporate or provide access to SNOMED CT. Provision of publicly available SNOMED CT browsers and related services to the end users is subject to the SNOMED CT licensing implications[228]. Providing access to SNOMED CT (or its derivatives) to the end users requires that terms of using SNOMED CT be observed and sub-license agreement be concluded.

The right to grant sub-licenses on use of the International Release to the end users is allowed to the extent as necessary for use of the Licensee Products, created under the Affiliate License Agreement[229]. Any sub-license shall be accessory to and may not extend the scope of license and duration of the Affiliate License Agreement[230].

Terms of the SNOMED CT sub-license agreement shall be presented to and accepted by the end users as a pre-condition of accessing the SNOMED CT or its Derivative[231]. The SNOMED CT use terms may also be presented as part of a license agreement governing use of the Licensee´s Products[232].

A template of the sub-license agreement for free publicly available browsers may be found at: www.ihtsdo.org/browser_license_guidance.pdf.

All sub-licenses granted to the end users for use of SNOMED CT in connection with the Licensee Products shall be recorded in a special register. This register may be inspected and shall be kept available for inspection by the IHTSDO upon request[233].

---

[227] Appendix B ALA.

[228] IHTSDO, Guidance on Provision of Publicly Available SNOMED CT Browsers and Related Services

[229] Clause 2.1.5 ALA.

[230] Clause 2.5 ALA.

[231] Paragraph 1 Appendix 1 Guidance on Provision of Publicly Available SNOMED CT Browsers and Related Services.

[232] Ibid.

[233] Clause 8.8 ALA.

3.2.4.5 IPR regulations related to SNOMED CT

Creation of works - derivatives or extensions - based on SNOMED CT give rise to the IPR. As the Affiliate License Agreement provides[234], all IPRs in all extensions and derivatives produced by the Licensee under the Affiliate Licence Agreement shall be owned by the Licensee. Other rules may apply if extensions or derivatives are standards-based.

As regards IPR in standards-based extensions, the IHTSDO preserved the right to request transfer of the IPR in such works to the IHTSDO itself or its nominated Member and the Licensee shall comply with the request and transfer its IPRs, as requested[235]. Almost the same relates to the IPR in standards-based derivatives, with the allowance, that the Licensee has a right to agree the IPR transfer at his sole discretion[236].

With transfer of the IPR also the obligation to maintain and distribute standards-based extensions and derivatives passes from the Licensee to the IHTSDO (or nominated Member)[237]. Along with that, license back in those works must be provided or procured by the IHTSDO to the Licensee, upon the term, however, until that extension or derivative becomes part of the International or National Release, *"as the case may be*"[238].

The IPR regulation relates also to the distribution of products or provision of services related to SNOMED CT. All media or documentation associated with distribution of the Licensee products or services related to SNOMED CT must be provided with the following notice:

> *"This material includes SNOMED Clinical Terms® (SNOMED CT®) which is used by permission of the International Health Terminology Standards Development Organisation (IHTSDO). All rights reserved. SNOMED CT®, was originally created by The College of American Pathologists. "SNOMED" and "SNOMED CT" are registered trademarks of the IHTSDO."*[239]

Use of the marks "SNOMED" and "SNOMED CT" is allowed to the extent only, as necessary to distribute products or provide services, created by the Licensee under the Affiliate License Agreement, and only to the benefit of the IHTSDO[240].

---

[234] Clause 3.4 ALA.

[235] Clause 3.5 ALA.

[236] Clause 3.6 ALA.

[237] Clause 3.7.1 ALA.

[238] Clause 3.7.2 ALA.

[239] Clause 8.3.1 ALA.

[240] Clause 8.4 ALA.

3.2.5 Conclusions

From the legal analysis above following conclusions can be made.

Use of external data sources in EURECA in a way that data from such external data sources - in whole or substantial parts - are incorporated or made available to the public in or via EURECA may fall under acts protected by third parties rights and sui generis database right, in particular. For such re-use authorisation of the right holder is required.

A legal advice for EURECA would be to use external data sources strictly to the extent as allowed by the terms of normal use. The terms under which external data sources are provided for use (or made available to the public) must be observed and complied with. If the extent of using external data sources in EURECA extends the scope of normal use and/or if there is a risk that by such use rights of third parties might be infringed, a legal advice would be to contact the right holder and, if necessary, negotiate additional license. The license scope shall be sufficient to cover uses of such external data sources which would be necessarily infringed by EURECA.

Extraction or mapping the terms from SNOMED CT with the semantic core dataset in EURECA is most likely to form a derivative of SNOMED CT. As such it is subject to the licensing policy of the IHTSDO. Development and providing software services and tools, which incorporate or provide access to SNOMED CT, to the public is also subject to the licensing policy applicable to SNOMED CT. For this, the Affiliate License Agreement must be concluded and complied with. The scope of Affiliate License is deemed as sufficient to cover the EURECA activities and prospective options of exploitation in full.

EURECA may benefit from its status as a research project in the medical domain and be released from the obligation to pay fees for use of SNOMED CT in Non-Member countries. For this, along with conclusion of the Affiliate License Agreement, an application for a fee waiver with justifying EURECA as a “Qualifying Research Project” must be submitted and confirmed by the IHTSDO.

Use of SNOMED CT in the EURECA core data set and provision of publicly available services and tools, which incorporate or provide access to SNOMED CT, shall comply with the IHTSDO standards and regulations, IPR policy and licensing requirements. Users of EURECA products and services related to SNOMED CT shall be provided with the SNOMED CT sub-license terms and be required to accept these prior to accessing such products and/or SNOMED CT, as part of these. Notices declaring that product or service uses SNOMED CT and its origin must be displayed as well.

Shall the scope of use of external data sources in EURECA go beyond the scope of use, as covered by the UMLS License, or if EURECA Parties intend to provide their tools or services, which may incorporate or provide access to the external data sources, used in EURECA, beyond the EURECA lifetime, a legal advice would be to check in how far the intended use is covered by the UMLS License, to consult the relevant right holders and, shall adequate license be needed, to negotiate a separate license, as right holders of relevant sources may require.

3.3 IPR issues relating to software and licensing

3.3.1 Protection of software

The objective of this part is to analyze the legal protection of software, ICT tools and other achievements generated in EURECA, which are implemented by means of software and might stand the criteria of patentability. The relevant regimes are copyright law, patent law, and undisclosed information. Protection of inventions conceived within the Project, which implies exploring the opportunities for patent protection, is explicitly addressed in WP 10 T 10.4. Therefore, protectability of software by patent law will only be analysed in general. Particular emphasis will be placed on patentability of Computer Implemented Inventions (CII).

3.3.2 Protection of computer programs under copyright

3.3.2.1 Protectable subject matter in EURECA

Most services and ICT tools in EURECA are built with the use of software. For example, interfaces towards external systems (WP2), tools for information extraction, services and API for querying the data from external data repositories (WP3), software services for enrolment of patient into clinical trials (WP 6), etc. would make software related products.

For the purposes of EURECA the term “software” is defined as a “*program being sequences of instructions to carry out a process in, or convertible into, a form executable by a computer, and fixed in any tangible medium of expression*”.[241] This definition implies that the software involves or stands for a computer program. In common practice and for the purposes of this Deliverable, both terms “software” and “computer program” are used synonymously.

Technically speaking, however, a computer program is rather a single unit of software and an end product of software development, while software is usually made up of a set of programs, algorithms, procedures which are operated by the system having data processing capabilities[242].

In the IT Industry, “software program” means “*a software item as any identifiable part of a software product”.* Software product means

“a product which is composed of a set of computer programs; in addition to programs, may also include the associated procedures, documentation, or data; may be part of

[241] Article 1.2 CA.

[242] Enriquez A., DYNAMIC LINKED LIBRARIES: Paradigms of the GPL license in contemporary software, 2013.

another software product, may be used to develop other software products, or may be a product that has been designated for delivery to customers"[243].

The primary type of protection for software is copyright.

3.3.2.2 Legal framework

Computer programs are protected by copyright law on an international and European level. The main principles of copyright are contained in the Berne Convention and in the TRIPS Agreement. The EU and its member states are parties to both.

Protection of literary and artistic works, as initially granted by the Berne Convention, is extended to the computer programs by the Article 4 WCT and Article 10 of the TRIPS Agreement. These extensions are usually referred to as Berne Plus. WCT also introduces supplementary provisions applying to technological measures[244] and Rights Management Information[245].

The main legal framework for protecting rights in computer programs on the European level is set forth in: Directive 2009/24/EC of 23 April 2009 on the legal protection of computer programs (Software Directive), Directive 2001/29/EC of 22 May 2001 on the harmonization of certain aspects of copyright and related rights in the information society, Directive 2006/115/EC of 12 December 2006 on rental right and lending right and on certain rights related to copyright in the field of intellectual property, Directive 2004/48/EC of 29 April 2004 on the enforcement of intellectual property rights

3.3.2.3 Basic criteria of protection by copyright

Intellectual property rights in software derive in general from copyright, which protects the expression of particular ideas[246] but does not protect *"the ideas and principles which underlie any element of a program"*[247], as such. "*This limitation to the expressions of an idea is the principal distinction between the applications of patent and copyright"*[248]*.* Copyright protection starts with creation and expression of the work and is not subject to any formality[249].

---

[243] Praxiom Research Group Limited, ISO IEC 90003 2004 PLAIN ENGLISH DEFINITIONS, unofficial translation into plain English, available at: http://www.praxiom.com/iso-90003-definitions.htm#Software%20product.

[244] Article 11 WCT.

[245] Article 12 WCT.

[246] Laurent A.M.St., Understanding open source and free software licensing, 2004, p. 24.

[247] Recital 11 Software Directive.

[248] Laurent, supra, p. 2.

[249] Article 5 Berne Convention.

To be protected by copyright, a program must qualify as a copyright work itself and must for this, first of all, meet the general criteria of copyright law, i.e. be an original expression of intellectual creation.

Article 1 Software Directive provides that protection shall apply *"to the expression in any form of a computer program"*[250], provided *"it is original in the sense that it is the author's own intellectual creation. No other criteria shall be applied to determine its eligibility for protection"*[251].

Taken that most programs are written in programming languages which are composed of certain symbols, letters, numbers, etc., and which are not protected as such, the way a program is written must be an intellectual creation:

"*The keywords, syntax, commands and combinations of commands, options, defaults and iterations consist of words, figures or mathematical concepts which, considered in isolation, are not, as such, an intellectual creation of the author of the computer program (...). It is only through the choice, sequence and combination of (…) words, figures or mathematical concepts (…) the author may express his creativity in an original manner and achieve a result (…) which is an intellectual creation"*[252].

In contemporary software development many programs are released open source. In the open source community frequently many authors work on the same piece of software.

Most Free and Open Source Software (FOSS)[253] licenses such as GNU General Public License, Apache License, MIT License, BSD License, etc. require authors to provide their contributions or modifications together with the respective copyright notices so that modifications are traceable. This is to ensure that the contribution of a particular author functions, that bugs can be fixed or advice asked for.

Moreover, software is mostly developed on the basis of mathematical concepts and principles. Following Recital 11 Software Directive:

"ideas and principles which underlie any element of a program, including those which underlie its interfaces, are not protected by copyright (…) to the extent that logic, algorithms and programming languages comprise ideas and principles, those ideas and principles are not protected."

Hence, for the purposes of copyright protection how the author constructs a program must be beyond the level of mere idea or logic.

---

[250] Article 1 Paragraph 2 Software Directive.

[251] Ibid, Article 1 Paragraph 3.

[252] ECJ, Judgment of 16.07.2009, *Infopaq International A/S v Danske Dagblades Forening*, Paragraph 45.

[253] A list of licenses, certified as open source, is available at Open Source Initiative (OSI), Open Source Licenses: http://opensource.org/licenses.

Copyright protection covers "neither the functionality of a computer program nor the programming language and the format of data files used in a computer program in order to exploit certain of its functions[254]." These elements do not *"constitute a form of expression of that program and, as such, are not protected by copyright in computer programs."*[255]

It is the main idea of copyright to protect the expression against copying. Hence, copyright protection is also limited to the expression. If protection of functionality of software or certain inventive methods implemented by software is sought, protection by patent law might be a more adequate solution.

3.3.2.4 Object and scope of protection

Protection by copyright begins with creation of a work, i.e. expression, and is not subject to any formality. The minimum term of protection is 50 years after the death of the author[256], the usual term of protection by copyright within EU is 70 years p.a.[257].

However, in contrast to patent law, where the patentable subject matter[258] is defined by the respective claims, what constitutes a computer program protected by the copyright law is not defined.

Article 10 TRIPS Agreement identifies "*computer programs, whether in source or object code"* as protectable by copyright.

The WIPO Model Provisions on the Protection of Computer Programs (WIPO Model Provisions)[259] define a computer program as a *"set of instructions capable, when incorporated in a machine-readable medium, of causing a machine having information-processing capabilities to indicate, perform or achieve a particular function, task or result"*[260].

Article 1 Software Directive provides for protection to *"the expression in any form of a computer program"* which is also extended to cover the *"preparatory design material, understood as "work leading to the development of a computer program provided that*

[254] ECJ, Judgment of 02.05.2012, Case C 406/10, *SAS Institute Inc. v World Programming Ltd*.

[255] Ibid.

[256] Article 7 Berne Convention.

[257] Article 1 Directive 93/98/EEC of 29 October 1993 harmonizing the term of protection of copyright and certain related rights.

[258] Article 51 EPC.

[259] WIPO, Model provisions on the protection of computer software - 1978 - WIPO PUBLICATION, NO 814(E) - GENEVA: WIPO.

[260] Ibid, Section 1 (i).

the nature of the preparatory work is such that a computer program can result from it at a later stage"[261].

As the ECJ established, the object of copyright protection of a program is *"the expression in any form of a computer program which permits reproduction in different computer languages, such as the source code and the object code"*[262].

Hence, the primary software items that enjoy copyright protection are the source and the object code.

3.3.2.5 Additional protection of software elements under know-how

Source code of software may also be protected as know-how, as is the case in the US and Germany[263].

The legal regime of know-how protection is governed by Article 39 TRIPS Agreement. The main requirements for protection are secrecy, confidential treatment and economic value[264]. To be protected, the information must be kept concealed from the public domain and treated as an IP asset of the software development company.

This type of protection applies mostly in the domain of proprietary software, which is written for hire and marketed in object code only.

Source code developed by a company constitutes an IP asset. If the source code were to be revealed, competitiveness of the company would be weakened[265]. Consequently, the requirements for protecting source code as a trade secret are fulfilled[266].

Under the "work-for-hire" doctrine, the economic rights in software written by the programmers under an employment relation belong to the employer. The programmers are usually required to sign non-disclosure agreements prohibiting disclosure of proprietary information, as well as non-compete agreements, under which the programmers may not work for a competitor for a certain period after they leave the employer. Development of proprietary software is different from the development and release of software "open source"[267]. Open source software in many cases implies that the source code is contributed to the public. Hence it does not have the quality of

---

[261] Recital 7 Software Directive.

[262] ECJ, Judgment of 22 December 2010, Case C-393/09 *Bezpečnostní softwarová asociace v Ministerstvo kultury*, Paragraph 35.

[263] Lodigkeit, supra, p. 99.

[264] Article 39 Paragraph 2 TRIPS Agreement.

[265] Lodigkeit, supra, p. 101.

[266] Ibid.

[267] Laurent, supra, p. 169.

being secret.[268] As a result, by being made public, open source code cannot be secret and protected by know-how.

Even when a company makes software using in part open source code and uses its software internally or markets it in object code only, because part of the code is already known it is unlikely that the source code will as a whole be recognized as a trade secret.

3.3.2.6 Moral rights of the author

The traditional rights under copyright cover the moral rights and economic rights granted to the author. Moral rights cover the rights "*to claim authorship; to object to certain modifications and other derogatory actions (…) which would be prejudicial to his honor or reputation*"[269]. The moral rights belong to the author and shall protect his reputation.

Following Article 6bis Paragraph 1 Berne Convention,

"independently of the author's economic rights, and even after the transfer of the said rights, the author shall have the right to claim authorship of the work and to object to any distortion, mutilation or other modification of, or other derogatory action in relation to, the said work, which would be prejudicial to his honor or reputation".

In contrast to the economic rights, which may be transferred, the moral rights are inalienable from the author, except by succession[270].

In contrast to proprietary software, which is primarily motivated by economic incentives, open source software related to research is developed by "*volunteers who have dedicated huge amounts of time, and, in many cases, significant parts of their lives to the development and distribution of good code for the benefit of as many people as possible*"[271].

Integrity of the author´s source code is one of the principles of open source software: "*The license may require derived works to carry a different name or version number from the original software*"[272]. Most FOSS licenses require that copyright and attribution notices be attached to new contributions in order to "*protect users and to protect reputations of work against injury arising from flawed derivative works*"[273].

---

[268] Lodigkeit, supra, p. 99.

[269] Article 6 bis Berne Convention

[270] Ibid, Paragraph 2.

[271] Laurent, supra, p. 158.

[272] Open Source Initiative (OSI), The Open Source Definition, Section 4, available at: http://opensource.org/osd

[273] Laurent, supra, p. 39.

Indeed, *"GPL requires that modified versions be marked as changed (…) for both users' and authors' sake (…) and explains this requirement in a way so that their problems will not be attributed erroneously to authors of previous versions"*[274].

3.3.2.7 Conclusions for EURECA

Third-party open source code is used as part of or basis for developing software for EURECA. Once an attribution requirement is present in the license of the code used, copyright notices attached to the code, along with the contributor´s one, where required by the license, must be provided along with the code. "*One principle, which is universally accepted, is that taking someone else´s work and modifying or distributing it in disregard of the intent of the author is wrong"*[275]. Using code in breach of its license is likely a copyright violation, resulting in termination of rights in the code[276] and depriving the violator of legal remedies to in turn enforce copyright in the code he contributed[277].

3.3.2.8 Economic rights of the right holder

While the rule of first ownership states that copyright belongs to the creator, a different regime applies to programs written in an employment relationship. Here, a work-for-hire doctrine applies, according to which the economic rights pass to the employer.

"Where a program is created by an employee in the execution of his duties or following the instructions given by his employer", by virtue of Article 2 Paragraph 3 Software Directive, *"the employer exclusively shall be entitled to exercise all economic rights in the program so created, unless otherwise provided by contract"*.

The economic rights to programs are to a large extent adapted to the digital environment, as noted in Agreed statements concerning Article 8 WCT. The basic rights in programs encompass the right of reproduction, distribution, making available to the public[278] rental[279], reproduction, translation, adaptation, arrangement and any other alteration[280] as well as other rights which may be granted by the national laws.

Software shall be written for the Project by employees of Parties. Under the work-for hire doctrine, as applicable to EURECA, it will be the Parties, who by virtue of Article

---

[274] Preamble GPL v3, available at: OSI, GNU General Public License, version 3 (GPL-3.0), http://opensource.org/licenses/GPL-3.0

[275] Laurent, supra, p. 159.

[276] Section 4 GPL v2; Section 8 GPL v3.

[277] Laurent, supra, p. 156.

[278] Directive 2001/29/EC of 22 May 2001 on the harmonisation of certain aspects of copyright and related rights in the information society.

[279] Directive 2006/115/EC of 12 December 2006 on rental right and lending right and on certain rights related to copyright in the field of intellectual property.

[280] Article 4 Software Directive.

2(3) Software Directive shall hold the economic rights in the software and have the right to license it further.

As regards sharing of rights in jointly generated software, referred to as Foreground in the meaning of Article 1.2 CA, so unless the contributing Parties conclude a separate agreement, the contributors shall own and exercise their IPR and licensing rights in jointly generated Foreground jointly, as governed by Article 4.1.2 CA.

Most FOSS licenses provide for the rights of use, reproduction, distribution, modification (making derivative works) and distribution of derivative works to the licensees. However, certain licenses, so called copyleft licenses like GPL or the Mozilla Public License, provide rights upon the condition that any further redistribution of the original program or derivative works based on the original program be subject to the same license terms of the original program. A copyright holder can grant his rights in a program to different licensees under different license terms. "*It is also possible for the copyright holder to make it available for licensing under a proprietary fee-based license option, as well as open source license option, such as GPL*"[281].

Hence, the Parties which hold the right in software they produce for EURECA need to consider the opportunity of dual licensing and decide on the license terms under which they wish to intend to release their software. For this, releasing the software within the Project as open source and externally under a proprietary basis may be an option.

As a licensing option, Apache License v.2 is suggested. On the one hand, it allows the software be distributed on commercial scale, for instance, under proprietary license, with the source code being closed[282]. It may be a good option for commercial distribution. On the other hand, it allows the software be released "open source" and royalty-free. This open source variant might be relevant for releasing software into the Project. Also, Apache License v.2 addresses the patent rights and protects the licensors and downstream licensees from claims on patent infringement, which might arise by use of the licensed software[283]. For further explanation, why Apache License v.2 is recommended for use and what options it provides please see Part 3.3.8 of this Deliverable.

However, when in some cases, choosing a license and proprietary licensing may be an option, in other cases, licensing of the resulting software may be predetermined by the license of original code used, as by use of GPL licensed code may be. "*Prior work on similar projects in many situations will provide a foundation for a new project*"[284].

Open Source licenses may allow commercial distribution (e.g. BSD License, Apache License), some require licensing only royalty-free (e.g. GPL), some licenses permit

[281] Rowland D., Information Technology Law, 2012, p. 421,

[282] Laurent, supra, p. 14.

[283] Section 3 Apache License v.2, available at: OSI, Apache License, Version 2.0, http://opensource.org/licenses/Apache-2.0.

[284] Laurent, supra, p. 175.

release of modified software with the source code closed (e.g. BSD License, Apache License, MIT License), some licenses require that source code of original and modified software be offered for use (e.g. GPL, Mozilla Public License, Eclipse Public License, etc.).

As regards commercial distribution of GPL covered software, so the GPL license does not provide an option for licensing GPL covered programs on a proprietary basis Rather, GPL covered programs shall be provided free of charge and charging royalties is excluded. On the other hand, fee for transfer of the program copies or servicing support or warranty protection may be provided for a fee[285].

One of the exploitation options would be to charge fees for distributing the copies. For instance, when programs are distributed from the site, fees for distributing copies can be charged, if the binaries are distributed by download. However, "equivalent access" to download the source, must be provided as well and *"the fee to download source may not be greater than the fee to download the binary"*[286].

Offering warranty protection and additional liabilities would be another exploitation option for GPL software. Section 15 GPL v.3, Section 12 GPL v.2 allow that warranty protection can be stated in writing by the copyright holders and/or other parties. Hence, provision of warranties could be evidenced by signing an agreement. The licensor, who provides warranties and accepts additional liability, acts at his own risk and accepts to bear *"the cost of all necessary servicing, repair and correction"* , should the program prove defective.

Therefore, the license terms underneath the code used and license for the software release need to be studied and considered by the Parties themselves on a case by case basis with a view on software exploitation options.

3.3.3 Protection of software under patent law

The objective of this part is to provide general legal guidelines on the criteria which apply for patenting inventions, what subject matter is patentable and what rights are granted by patent law. The main emphasis is given to patentability of computer implementing inventions.

3.3.3.1 Legal framework

On the level of international law the main legal documents which provide for protection of inventions by patents are the Paris Convention for the Protection of Industrial Property of 20 March 1883[287], the Patent Cooperation Treaty (PCT) of 19 June

[285] Section 1 GPL v.2, Section 4 GPL v.3.

[286] GNU, Frequently Asked Questions about the GNU Licenses, available at: https://www.gnu.org/licenses/gpl-faq.html.

[287] WIPO, Law and Treaties, Paris Convention for the Protection of Industrial Property, available at: http://www.wipo.int/treaties/en/text.jsp?file_id=288514.

1970[288], and the TRIPS Agreement, Section 5 Article 27 et seq. The legal documents which govern the protection of inventions under patent law in the EU is the European Patent Convention (EPC)[289].

Article 52 EPC provides: *"European patents shall be granted for any inventions, in all fields of technology, provided that they are new, involve an inventive step and are susceptible of industrial application"*.

3.3.3.2 Patentable subject matter in EURECA

In contrast to copyright, which is bound to an expression of an idea, "*a valid patent does not protect the expression of an idea, but the underlying substance of it*"[290]. In relation to a microchip, a patent would not protect the expression of the chip itself, but "*the idea that given circuits can be organized and made to operate in a particular way. Because of their potentially vast scope patents are construed more strictly, require a registration process, and last for shorter periods than copyrights*"[291].

Protection of software under patent law is one of the options for protecting EURECA results[292]. EURECA has its IT infrastructure and ICT tools, which have software as the basis of operation[293]. The patentable subject matter in EURECA is most likely to be represented by innovative solutions, processes and methods for data processing that are implemented by means of a computer.

The practice of patenting software is highly controversial both in the US and Europe. What makes patenting software even more complicated is that "*programs for computers… as such*" along with "*schemes, rules and methods for performing mental acts, playing games or doing business"* are excluded from patenting in the EU by virtue of Article 52 (2)(c) EPC. However, whereas patentability of computer programs as such is excluded, what can be patented are the so-called computer implemented inventions.

Certain innovative solutions, decision support systems, etc. in EURECA may be considered for patenting, as expressly addressed in the DoW, WP 10, Task T10.4.

---

[288] WIPO, Law and Treaties, Patent Cooperation Treaty, available at: http://www.wipo.int/pct/en/texts/articles/atoc.htm.

[289] Convention on the Grant of European Patents (European Patent Convention) of 5 October 1973, as revised by the Act revising Article 63 EPC of 17 December 1991 and the Act revising the EPC of 29 November 2000, available at: EPO, Law and Practice, Legal Texts, The European Patent Convention: http://www.epo.org/law-practice/legal-texts/html/epc/2013/e/ma1.html.

[290] Laurent, supra, p. 2.

[291] Ibid.

[292] DoW, WP 10, T. 10.4.

[293] Collaborative Project, Part B, p. 7.

The following fields of technology related to CII in the medical domain can be considered: computer technology, IT methods for management, G06F 19/00 Digital computing or data processing equipment or methods, specially adapted for specific applications[294].

3.3.3.3 Patentability criteria

As follows from Article 52 EPC, the basic patentability criteria in the EU are novelty, an inventive step, industrial applicability and relation to technology. Inventions which stand these criteria and are not elsewhere excluded from patenting can be considered as patentable subject matter.

Each of these requirements has a specific, very technical meaning. Whether a certain invention meets these criteria is established in the patent examination procedure. The invention filed for patenting is analysed against the background of the inventions constituting the state of the art. The assessment is done by a person skilled in the art (i.e. within the technical field concerned) and is a prerogative of patent attorneys.

The criterion of novelty is defined in Article 54 EPC: "*An invention shall be considered to be new if it does not form part of the state of the art".* Novelty of an invention is assessed against the prior art, which is considered to "*comprise everything made available to the public by means of a written or oral description, by use, or in any other way, before the date of filing of the (…) patent application"*[295]. Here, any data published or made available to the knowledge of general public on a worldwide scale by means of publications (scientific literature), exhibitions, articles, patent disclosures (patent databases) are considered.

An invention has an inventive step (so-called "non-obviousness" in US patent law), "*if, having regard to the state of the art, it is not obvious to a person skilled in the art"*[296]*.* Inventive step suggest that an invention must substantially differ from what was invented before[297]*.*

An invention is capable of industrial applicability, provided "*it can be made or used in any kind of industry, including agriculture"*[298]*.* Another implicit requirement for patenting inventions comes from Article 52 Paragraph 1 EPC, which provides that patents be granted to inventions "*in all fields of technology".* By this, relation to technology is considered to be another requirement of patentability.

Another important criterion which the invention must fulfil in order to be patented is that it must not be excluded from being patentable. Article 52 Paragraph 2 (c) EPC

[294] See e.g. Section G of the International Patent Classification.

[295] Article 54 Paragraph 2 EPC.

[296] Article 56 EPC.

[297] Deutsches Patent- und Markenamt, Patent protection, What is the purpose of patent protection, available at: http://www.dpma.de/english/patent/patent_protection/index.html.

[298] Article 57 EPC.

provides that "*schemes, rules and methods for performing mental acts, playing games or doing business, and programs for computer*" as such shall not be regarded as patentable inventions.

Exclusion of computer programs from patenting creates a legal obstacle for patenting software, which, however, may be overcome, provided the

"subject-matter for which protection is sought (…) has a 'technical character' or (…) involves a 'technical teaching', i.e. instruction, addressed to a technically skilled person as to how to solve a particular technical problem using particular technical means. The problem solved by the invention must thus be technical, in contrast for example to a purely financial, commercial or mathematical one"[299].

Whereas only computer programs "as such" are excluded from patenting, and there is no precise definition of "invention", inventions which solve technical problems or are technical in substance or may be realized by a computer are not excluded from patentability. The EPO case law says that *"controlling or carrying out a technical process is not excluded from patentability, irrespective of whether it is implemented by hardware or by software"*[300].

3.3.3.4 Computer implemented inventions

"A computer-implemented invention is one which involves the use of a computer, computer network or other programmable apparatus, where one or more features are realised wholly or partly by means of a computer program."[301]

A technical effect may be derived when the "*interaction between the computer program and the computer hardware on which it is run*" solves some technical problem and goes beyond the "normal" physical interaction. A technical effect may also result from "*the control of an industrial process or the working of a piece of machinery, but also from the internal functioning of the computer itself (e.g. memory organisation, program execution control) under the influence of the computer program"*[302].

As regards the requirement of technological relation, the technical character is assessed from technical and non-technical features, which together comprise an invention. The evaluation is done on a case-by-case basis by the patenting office[303].

---

[299] European Patent Office, News and Issues, Patenting issues, Patents for software? European law and practice, Computer-implemented inventions, People often talk about software patents – what exactly do they mean?, available at: http://www.epo.org/news-issues/issues/software.html.

[300] Ibid.

[301] Ibid.

[302] Ibid.

[303] Ibid, Some landmark case law decisions, Two identities/Comvik (T 641/00).

Here are some practices of the European Patent Office (EPO): simulation methods based on mathematical constructs and implemented by a computer by means of circuit simulations are considered to possess technical character, because "*circuit simulations (…) form an essential part of the circuit fabrication process"*[304]*.* Also, "a *computer-based method of completing a transaction in the course of commercial activity was patentable only if, beyond the proposal to use a computer as a means of processing the data needed to complete the transaction, the claim contained other instructions based on a specific technical problem making it possible to establish as part of the assessment of inventive step whether there was any technical contribution justifying patentability"*[305]*.*

As regards CII in the medical domain, the following subject matter was filed for patenting but denied: *"[A] method for processing medically relevant data for patient examinations (…) characterised by a program installed in a data-processing device which, on the basis of entered (...) information and using a (…) database, selected one or more modalities for patient examinations. These modalities were then communicated to an output device, with the database selecting and communicating one or more examination or measurement protocols defining the manner in which a particular examination was to be conducted"*[306].

Patentability of the claimed method was denied because the method was construed as a "*method for performing mental acts"*, excluded from patentability by Article 52 Paragraph 2 (c) EPC, and lacking technical features. The method related "*to the correct choice of examination modalities (e.g. X-ray, computer tomography, magnet resonance) and (…) their purpose-related order of application on the patient by means of a program using a symptom-specific and/or diagnosis specific database".* The choice of modalities and purpose-related order of application by means of a program were treated as elements of data processing. These are non-technical in nature and serve only to "automate" the doctor's decision. A technical problem, which an invention solved, was not found.

This illustrates that at the heart of patenting CII lies a technical problem, which an invention has identified and will solve: *"[I]t was not the use of a computer program itself, but rather the solution of such a problem with the aid of a (programmed) computer which could render an invention patentable (…) the decisive point was whether, taking the requisite overall view, the teaching served to solve a specific technical problem consisting of more than just data processing"*[307].

---

[304] Ibid, Circuit simulation I/Infineon Technologies (T 1227/05).

[305] EPO, Law and Practice, Case law from the EPC contracting states (2004-2011), BGH of 24 May 2004 (X ZB 20/03) – Online banking, available at: http://www.epo.org/law-practice/case-law-appeals/national-patent-decisions.html.

[306] Ibid, BGH of 20 January 2009, X ZB 22/07 – Equipment for selecting medical examination methods.

[307] Ibid.

The issue of patenting EURECA results will be specifically addressed in WP 10. However, the examination of EURECA results for patenting shall be conducted against the background of the above considerations and practice of the EPO. When examining the results for patenting, it shall be taken into account that the patentability requirements of novelty, an inventive step, industrial application and relation to technology need to be considered together because their cumulative effect is decisive.

3.3.3.5 Rights to a patent

Rights and right holders to a European patent are defined in Article 60 EPC. It provides:

"The right to a European patent shall belong to the inventor or his successor in title. If the inventor is an employee, the right to a European patent shall be determined in accordance with the law of the State in which the employee is mainly employed; if the State in which the employee is mainly employed cannot be determined, the law to be applied shall be that of the State in which the employer has the place of business to which the employee is attached".

The EPC grants in European patents *"the same rights as would be conferred by a national patent granted in that State"*[308].

The minimal set of rights which shall be conferred by a patent may be derived from Article 28 TRIPS Agreement. The rights shall comprise the exclusive rights to authorize or prevent unauthorized use of the patented product by *the acts of: "making, using, offering for sale, selling, or importing … that product… for these purposes"*[309]. Following the Footnote to Article 28, the importation right, "*like all other rights conferred … in respect of the use, sale, importation or other distribution of goods"* is subject to the principle of exhaustion, as provided for by Article 6 TRIPS Agreement.

The holder of a patent, "*where the subject matter of a patent is a process, shall have the exclusive right to authorize or prevent unauthorized using the process, and from the acts of: using, offering for sale, selling, or importing for these purposes at least the product obtained directly by that process"*[310].

The patent holder may assign, or transfer by succession, the patent and to conclude licensing contracts.[311] Hence, the Parties who generate patentable subject matter during the Project shall have the rights in the patent, once granted, and have the power to dispose of the rights as provided by the national law of the patent holder in place.

[308] Article 64 Paragraph 1 EPC.

[309] Article 28 Paragraph 1 (a) TRIPS Agreement

[310] Article 28 Paragraph 1 (b) TRIPS Agreement.

[311] Article 28 Paragraph 2 TRIPS Agreement.

Filing of patent applications by the Parties and exercise of these rights shall be subject to the terms of the CA, in particular as regards Joint Ownership, as provided for in Article 4.1.2.2. CA.

Patent applications related to the results which are generated by the Project and which are filed by or on behalf of the Parties shall be subject to and reported to the Commission in accordance with Article GA II 4.2 and Article GA II 28.2 paragraph 2. Hence, the patent applications concerned must indicate that these were created with financial assistance of the Union and be provided with the statement, as defined in Article GA II 28.2 paragraph 2.

3.3.3.6 Software patents and licensing issues

In contrast to copyright, which is not subject to any registration requirements and which is relatively easy to acquire, the stronger protection granted by patent law requires patenting an invention, a time consuming and costly procedure. Companies which protect their rights in software by patents make that investment in exchange for monopoly rights, which will allow them to recoup the investment.

In the U.S., patents in software are rather common. However, the monopoly rights in patented software contradict the idea of open software development. Richard Stallman, founder of the Free Software Foundation, is of the opinion that patenting software is a

"vicious and absurd system that puts all software developers in danger of being sued by companies they have never heard of, as well as by all the mega corporations in the field. Large programs typically combine thousands of ideas, so it is no surprise if they implement ideas covered by hundreds of patents. Mega corporations collect thousands of patents, and use those patents to bully smaller developers. Patents already obstruct free software development"[312].

Specifically for this reason most FOSS licenses have specific provisions dealing with software patents.

Some FOSS licenses, such as Apache License v2 and GPL v3 explicitly grant patent rights to downstream licensees. For instance, Apache License v2[313] requires in Section 3 that each contributor grant to downstream licensees a

"perpetual, worldwide, non-exclusive, no-charge, royalty-free, irrevocable (except as stated in this section) patent license to make, have made, use, offer to sell, sell, import, and otherwise transfer the Work, where such license applies only to those patent claims licensable by such Contributor that are necessarily infringed by their Contribution(s) alone or by combination of their Contribution(s) with the Work to which such Contribution(s) was submitted".

[312] Stallman R., Why upgrade to GPL v3, available at: FSF, Licenses, Why upgrade to GPL v3: http://www.gnu.org/licenses/rms-why-gplv3.html.

[313] OSI, Apache License, Version 2.0, available at: http://opensource.org/licenses/Apache-2.0.

The grant of the patent license from the upstream licensors is made conditional upon the obligation of the downstream licensees not to sue. Once a patent claim is filed, "*any patent licenses granted to You under this License for that Work shall terminate as of the date such litigation is filed*"[314]

GPL v3[315] in Section 11 also imposes on each contributor an obligation to grant a *"non-exclusive, worldwide, royalty-free patent license under the contributor's essential patent claims, to make, use, sell, offer for sale, import and otherwise run, modify and propagate the contents of its contributor version".* By this GPL v3 prevents software from being made effectively proprietary via the use of patents.

"The explicit patent license of GPLv3 makes sure companies that use the GPL to give users the four freedoms cannot turn around and use their patents to tell some users, 'That doesn't include you.' It also stops them from colluding with other patent holders to do this".[316]

Patent protection by a software license is not absolute; counteraction with third party patents may come into play.

"*There may be patent claims that apply to the licensed software but are known to neither the licensor nor the licensee. Because licensors can only license works that belong to them, the existence of a particular software license is no protection for the licensee against claims in infringement that are brought not by the licensor but by a third party patent holder*"[317].

GPL v2 does not mention patent grants explicitly,

"instead, GPL simply states what would be true in any event - a mandate derived from patent law or an agreement to license patent rights that is inconsistent with the terms of the GPL does not absolve the licensee from complying with those terms"[318].

Or in GPL v2's own words,

"if a patent license would not permit royalty-free redistribution of the Program by all those who receive copies directly or indirectly through you, then the only way you

[314] Section 3 Apache License v2.

[315] OSI, GNU General Public License, version 3 (GPL-3.0), available at: http://opensource.org/licenses/GPL-3.0.

[316] Stallman R,Why upgrade to GPL v3, supra.

[317] Laurent, supra, p.8.

[318] Nimmer, R.T, Legal Issues in Open Source and Free Software Distribution, adapted from Chapter 11, Raymond T. Nimmer, The Law of Computer Technology, 1997, 2005 Supp., p.56.

could satisfy both it and this License would be to refrain entirely from distribution of the Program"[319].

In any case, if protection of EURECA results by patents is considered, this option shall be assessed carefully and measured against the Project's open source commitment and the terms of the open source licenses involved.

3.3.3.7 Conclusions

In summary, it may be concluded that protecting EURECA results by patents is possible. The protectable subject matter must most probably be represented by CII. By assessing the protectable subject matter for patent protection, it must be verified whether the product or process will stand the patentability criteria, i.e. be novel, susceptible of industrial application, include an inventive step and solve a technical problem. Moreover, benefits of patent protection shall also be compared to software licensing in general and open source licensing in particular.

3.3.4 Software licensing issues within the Consortium

Some legal issues may concern the use of software developed by the Parties in the Project, some may be triggered by use of external software for the Project and, last but not least, by the exploitation of ICT tools and services developed by EURECA. Certain legal aspects relating to software are handled by the terms of the CA. Certain legal issues, in particular relating to the use of open source software, go beyond the legal framework of EURECA and will be considered within copyright law in general.

In this part software licensing issues relating to performance of the Project and use of software after the Project completion will be considered. For this, licensing arrangements between the Parties of the Consortium as well as licensing of external software for use in the Project will be analysed. Analysis of the licensing arrangements with respect to use of the software by the Parties will be done against the background of legal terms granting Access Rights to Software, as provided for by CA. In view of EURECA's open source commitment, licensing and use of external software and tools as well as license compatibility issues will be outlined.

3.3.5 Software license and Access Rights

The terms relating to use of software in the Project are mostly regulated by the CA and are subject in general to the legal provisions governing Access Rights, Section 4.2 CA, and Access Rights to Software, Section 4.2.7 CA. The most essential terms of the software license agreement are incorporated in the CA.

3.3.5.1 Software license

Software license agreements are governed and concluded on the general principles of contract law. To make an enforceable agreement, the parties shall, as a rule, agree at least to certain terms without which the agreement cannot be deemed as concluded.

[319] Section 7 GPL v2, available at: OSI, GNU General Public License, version 2 (GPL-2.0), http://opensource.org/licenses/GPL-2.0.

Such terms are considered to be the main obligation, the reciprocal obligation, usually a financial consideration, and term of the agreement. However, regulations on conclusion of contracts under the national laws may vary.

There are no mandatory provisions on the essential terms of a software license agreement prescribed by European law.

Typical terms of a software license agreement are: the parties, the software as the object of license, modes of use of the software, the object or source code, in which the software shall be released, the right to sublicense and assign the license, duration, territorial scope, financial terms, confidentiality provisions, liability and exemption clauses, other provisions which the parties deem reasonable to agree, e.g. maintenance and service[320].

The terms relevant for a software license agreement are laid down in the CA, in particular, within terms that govern the Access Rights (Section 4.2 CA) and Access Rights to Software (Section 4.2.7 CA).

As follows from the general principles on Access Rights, a non-exclusive software license shall be granted either for execution of the Project or for Use; a license for Use shall apply on a worldwide basis (Article 4.2.1 CA). The term within which the Access Rights may be requested and granted constitutes the duration of the Project and expires two years after the end of the Project, with exception of earlier termination (Article 4.2.1.5 CA).

Access to software, either for Project execution or for Use, both to Background (except software included in Annex 3 and Annex 5) and Foreground, shall, in general, be provided in form of Limited Source Code Access (Article 4.2.7.1 CA), i.e. object code and API, if required for use of the object code; the source code shall be released if the object code and API are unavailable (Article 1.2. CA). Software that is Background and which the Parties agree to release in the source code for Use is included in Annex 5. Provision of software documentation, porting software to a different platform or rendering of maintenance services are not included (Article 4.2.7.1 (b) CA). Software that is Background of the Parties and is not released into the Project is included in Annex 3.

According to Article 4.2.7.1 CA, which governs Access Rights to Software, access to software shall, unless agreed or provided otherwise, be given in the form of Limited Source Code Access, which means *"(a) access to Object Code; or, where normal use of such Object Code requires an API, access to such Object Code and such API; or (b), if (a) is not available, access to Source Code"*[321]. However, when license terms require that source code be granted to the licensees as of request, such software, usually "open source", will fall under the category of works under Controlled License Terms, as will be provided below.

[320] Rowland, supra, p.401.

[321] Article 1.2 CA.

3.3.5.2 Form of contract

The form in which a software license agreement must be concluded in order to be effective is not prescribed by the Software Directive. Hence, a software license agreement may be contracted in any form.

However, to have an evidentiary value in some national jurisdictions, like Germany[322], the agreement shall be executed in writing, i.e. signed with a handwritten signature or as certified by a notary. Also, the copyright laws of some EU Members States require that agreements as to future works and contracts concerning unknown types of exploitation require written form[323].

As stated in Article 4.2.4 (c) CA, Access Rights for Use shall be granted upon signature of the written agreement. The agreement made in writing shall prove that the rights have been granted. Grant of the Access Rights for execution of the Project is regulated in Article 4.2.3 CA. It says that the Access Rights are "*hereby requested (in accordance with the requirements of the GA), and shall be granted, as of the date of the GA entering into force, on a Royalty-Free basis to and by all Parties"*. By this formulation, Access Rights for execution of the Project can be considered as requested and granted via signing the CA. The CA, shall, in its turn, be evidence that the rights have been requested and granted.

Terms which regulate the use of software for execution of the Project or for Use are provided below.

3.3.5.3 Access rights for execution of the Project

Apart that the rights to software are provided on a non-exclusive basis and in form of Limited Source Code Access, the rights to software needed to perform the Project shall be granted on a royalty-free basis (Article 4.2.3 CA). The scope of rights which shall be granted for execution are not explicitly identified; however, the rights shall be granted "as needed" for the Project Execution, as laid down in Article 4.2.3 CA. This refers to such rights that are technically essential (Article 1.2 CA).

Where the scope of rights is not explicitly defined, the general national rules of interpreting agreements will apply. For instance, German law tends to interpret agreements by purpose. The Copyright Act of Germany[324] makes it clear that:

---

[322] Article 416 Code of Civil Procedure of Germany, as promulgated on 5 December 2005 (Bundesgesetzblatt (BGBl., Federal Law Gazette) I page 3202; 2006 I page 431; 2007 I page 1781), last amended by Article 1 of the Act dated 31 August 2013 (Federal Law Gazette I page 3533); available at: http://www.gesetze-im-internet.de/englisch_zpo/englisch_zpo.html.

[323] Article 40, Article 31 Act on Copyright and Related Rights of Germany (Copyright Act) of 9 September 1965 (Federal Law Gazette Part I, p. 1273), as last amended by Article 8 of the Act of 1 October 2013 (Federal Law Gazette Part I, p. 3714), available at: http://www.gesetze-im-internet.de/englisch_urhg/englisch_urhg.html#p0215; Reed C., Angel J, Computer Law, Sixth Edition, Oxford University Press, 2007, Paragraph 7.3.1. p. 352.

[324] Act on Copyright and Related Rights (Copyright Act), Copyright Act of 9 September 1965 (Federal Law Gazette Part I, p. 1273), as last amended by Article 8 of the Act of 1 October

"the types of exploitation have not been specifically designated when an exploitation right was granted, the types of use to which the right extends shall be determined in accordance with the purpose envisaged by both parties to the contract. A corresponding rule shall apply to the questions of whether an exploitation right has in fact been granted, whether it shall be a non-exclusive or an exclusive exploitation right, how far the exploitation right and the right to forbid extend, and to what limitations the exploitation right shall be subject"[325].

Also, when the contract on software development does not explicitly mention the software license, but the license is clear that the principal would need to use the software, UK court practice would interpret the agreement as including an implied license to use the software for the business purposes[326]. On the other hand, some national jurisdictions might tend to interpret agreements restrictively. Thus, the rights which are not explicitly negotiated as licensed or assigned might be considered as not granted at all.

Following Section 4.2.1 CA, the Parties shall grant such Access Rights in software, for both Background, unless excluded by Annex 3, and Foreground, that are needed for execution of the Project or Use of the Parties' Foreground (Article 4.2.1.4 CA).

3.3.5.4 Access rights for Use

Grant of Access Rights for Use is regulated in Article 4.2.4 CA and 4.2.7.2 CA. The license type (non-exclusive), territorial scope (worldwide) and access to software in form of Limited Source Code Access (object code and API, if required), are outlined above. The rights to use software (both Background and Foreground) for internal non-commercial use and research as well as educational activities shall be granted royalty-free (Article 4.2.4 Paragraph 1 CA).

Article 4.2.4 Paragraph 1 CA provides that the rights to Background for Use shall be granted upon Fair and Reasonable conditions. However, grant of the rights to Foreground for Use on Fair and Reasonable conditions is made conditional on reporting of the Foreground in accordance with Article GA II 28.2 Paragraph 2, which applies to the patent applications. Consequently, provided patent applications will not be filed for the software, the Access Rights to such software shall, following Article 4.2.4 Paragraph 2 CA, be provided royalty-free.

The rights shall, unless agreed otherwise by the Parties, be granted in the form of Limited Source Code Access (i.e. object code and API) and in the scope as set out in Article 4.2.7.2 CA. Hence, the rights in software for use, unless agreed otherwise, shall comprise the right to use software

---

2013 (Federal Law Gazette Part I, p. 3714), available at: http://www.gesetze-im-internet.de/englisch_urhg/englisch_urhg.html#p0146.

[325] Article 31 Copyright Act of Germany.

[326] Rowland, supra, p. 400.

"in research, to create/market any product/process and/or create/provide any service; to distribute, make available, market, sell and offer for sale (including by using the services of a third party) (…) alone or as part of or in connection with any products or services of the Party having the Access Rights".[327]

The right to make and have made an unlimited number of copies is also included.

Provided release of the source code to software that is Foreground is negotiated and agreed by the Parties, then the rights to such source code shall, apart from the rights outlined above and unless agreed otherwise, also comprise the right to use, modify and copy the source code, as may be required for exercise of the acquired rights in software (Article 4.2.7.2 (b) CA). The right to sublicense or release the source code to any third party, unless agreed, is excluded.

3.3.6 Sublicense to end-users

3.3.6.1 Rights of end-users

The Party who receives the right to use the other Party´s Foreground for Use shall have the right to grant to a customer of its Foreground an end-user license for necessary software as laid down in Article 4.2.7.2 (a) (iii) CA.

Article 4.2.7.2 CA deals with software licenses and sublicensing rights and provides that Access Rights for Use be granted to object code and/or an API. These Access Rights shall, according to item (iii), comprise the right "*to grant to each end-user customer buying/using such products/services a license: to use such Object Code and/or API".*

The rights granted to the end-users shall, according to Article 4.2.7.2 CA, include the right to use the software in part or in connection with normal use of the

"products/services of the Party having the Access Rights; to maintain such products/services; to create for its own end-use interacting interoperable Software in accordance with the rights conferred by, and subject to the conditions of, Counsel Directive of 14 May 1991 on the legal protection of computer programs (91/250/EEC) and to make and have made an unlimited number of copies".

The rights to software that shall be granted by the Parties to the end-users pursuant to Article 4.2.7.2 (a) (iii) CA are in line with the provisions of the Software Directive, which governs the end-user's rights in software that are not subject to authorization of the right holder. The rights "*necessary for the use of the computer program by the lawful acquirer in accordance with its intended purpose, including for error correction"* are granted to the end-users by virtue of Article 5 Software Directive. Hence, the acts of reproduction, "*translation, adaptation, arrangement and any other alteration of a computer program"*, including for error correction and making of a back up copy, which are essential for normal use of computer programs and which, under the copyright law are subject to the consent of the right holder, are exempted from the requirement to obtain such authorization by the law.

[327] Article 4.2.7.2 CA

The right of reproduction as necessary for normal use of the program implies that the lawful acquirer shall be allowed to copy the program

"as technically necessary for the use of that program (…) in accordance with its intended purpose (…). The acts of loading and running necessary for the use of a copy of a program which has been lawfully acquired, and the act of correction of its errors, may not be prohibited by contract"[328].

3.3.6.2 Error correction

Whereas the right of making a back up copy may not be prevented by the agreement[329], the rights of reproduction and modification of the software are exempted from the authorization, unless "*specific contractual provisions"*[330] apply. Hence, the parties can define in how far the end-user may exercise the rights of modification and reproduction in the end-user license agreement.

Although software is normally provided to the end-users in the object code only, any modification and error correction would normally require access to the source code.

"Whatever the extent of the right conferred by the Directive, it is not the acquirer´s right to have errors corrected; he or she can merely correct them without being in breach of copyright (…) there is no obligation for the seller to supply the source code… as needed for error correction (…) the Directive would not seem to make the source code available to the greater extent to the acquirer".[331]

Therefore, the Parties may provide maintenance of software to the end user under a separate service agreement and allow error correction at the discretion of the user. This shall be sufficient to satisfy requirements of the Software Directive.

3.3.6.3 De-compilation

The end-user's right of de-compilation, as foreseen in Article 4.2.7.2 (a) (iii) CA, is also included in the exempted acts of software use by Article 6 Software Directive "*where reproduction of the code and translation of its form (…) are indispensable to obtain the information necessary to achieve the interoperability of an independently created computer program with other programs."* The right of de-compilation may be exercised in limited scope and upon certain conditions, as provided in the Software Directive.

The idea is to make it possible *"for the end-user to connect all components of a computer system, including those of different manufacturers, so that they can work together (…) without prejudice to the right holder´s right"*[332].

---

[328] Recital 13 Software Directive.

[329] Article 5 Paragraph 2 Software Directive

[330] Article 5 Paragraph 1 Software Directive.

[331] Rowland, supra, p. 405.

[332] Recital 15 Software Directive.

As in the case with error correction, de-compilation of software suggests translation of the object code into the source code with subsequent porting it to the language of another computer program to achieve inter-operability. Therefore, the act of de-compilation implies that the end-user may also get access to the source code, but to the extent as strictly required "*to achieve interoperability of an independently created computer and those acts are confined to the parts of the original program which are necessary in order to achieve interoperability*"[333].

As regards the end-users rights in software, the Software Directive makes clear that such acts as de-compilation, making of a back-up copy or observation, study or testing of the functioning of a program may not be derogated by the agreement. "*Any contractual provisions contrary to the provisions of this Directive laid down in respect of the exceptions provided for by this Directive should be null and void*"[334].

3.3.6.4 Conclusions

The rights to sublicense software to the end-users, as provided for in Section 4.2.7.2 CA, shall enable the Parties to provide their customers with the rights necessary for use of the software under its intended purpose. The scope of rights is in line with the Software Directive. Whereas the right of making a backup copy and the right of de-compilation granted to the lawful users of computer programs by the Software Directive cannot be prevented by the agreement, the Parties have a certain leeway to regulate the scope of right to modification and error correction, especially considered that modification of software implies access to its source code as well.

The provisions of the CA which govern the end-users rights in software apply mostly to licensing software on proprietary basis. With respect to open source licensing, the license terms already contained within the license may apply instead. Open source licensing will be considered in more detail below.

3.3.7 Open Source Software and Software Licensing

EURECA uses open source software and is aware of the positive effects of using open source software for the research community. At the same time, EURECA also recognizes some of the more disadvantageous aspects of open source software use, in particular with regard to Access Rights[335]. The introduction and use of software and other copyright works, such as databases, subject to the Controlled License Terms[336], are subject to special regulations, reporting and unanimous approval of the Parties, as provided for by the CA[337].

[333] Article 6 Software Directive.

[334] Recital 16 Software Directive.

[335] Article 4.2.7.3 CA.

[336] Article 1.2 CA.

[337] Article 4.2.7.3 CA.

3.3.7.1 Controlled License Terms

The meaning of Controlled License Terms (CLT) is given in Article 1.2 CA as license terms relating to copyright works, including software, which require at least one of the following:

> (a) that the Source Code be made available as of right to any third party on request, whether royalty-free or not;
>
> (b) that permission to create modified versions or derivative works .. be granted to any third party;
>
> (c) that a royalty-free licence (…) be granted to any third party.

Given that only one of the above criteria is sufficient to make a license subject to Controlled License Terms, it is likely that some open source licenses might be implicated.

Release of software and other copyright works, such as databases, either as Foreground or Background, under license terms which qualify as Controlled License terms in the meaning of Article 1.2. CA, are subject to special regulations, as provided for in Article 4.2.7.3 (a) CA.

Such regulations require that works which are licensed under the Controlled License Terms (CLT works) prior to release be reported to the Parties, so that the Parties are made aware what work is concerned and in how far their duties and rights under the Project may be affected. The CLT work in question may be released once approval of the Parties is requested and use of the CLT work in the Project is unanimously agreed (Article 4.2.7.3 (a) (ii) CA).

A special procedure for contributing CLT works into the Project – subject to request and approval – shall enable the Parties to assess whether the "*Parties' utilisation or Use of or Access Rights to Background, or Foreground or other Work"* may be "*impaired or otherwise affected"*[338]. The request for approval shall essentially be made according to the form laid down in Annex 6 to the CA.

The right to sub-license the CLT work shall be either expressly agreed in writing by the Party granting the Access Rights, or be necessarily stated in the approval of request in accordance with Article 4.2.7.3 Paragraph (a) (iii) CA. It is necessary because exercise of the Access Rights may also be affected. The license requirement attached to the CLT work – either to release the source code, or grant the right on modification or royalty-free licensing – means that the same requirement must be complied with by any further re-distribution of the work concerned.

Hence, a Party which obtains the right on use of the CLT for Use of its own Foreground work via Access Rights, as provided for by the CA, will also be bound by the same license requirement. This means that with any further re-distribution of its own Foreground together with or in connection with the CLT work in question, it must

[338] Section 4.2.7.3 (a) (ii) CA.

comply with the said license requirement for the CLT work and forward it with the CLT work further.

The recommendation for the Parties which use open source software for the Project would be:

i. To check whether the license terms of the open source software (other works) meet one or more requirements laid down for Controlled License Terms (Article 1.2. CA);
ii. To check whether the license terms of the open source software (other works) affect its own software/work (whether its own work can be considered as a derivative (Article 1.2 CA, license terms concerned).
iii. Where the answer is in the affirmative, assess the chances whether use of its software/work would be approved by the Parties;
iv. Where those chances are assessed as negative, seek alternative solutions, i.e. software/works with alternative licenses, which are not subject to the Controlled License Terms.

From a practical perspective, the group of permissive copyright licenses such as BSD License, MIT License, Apache License and the like provide for rather lax terms of using the licensed software. They, as a rule, require that copyright notices, terms of license and disclaimer be retained, but do not require any of the acts, covered by the CLT. The software released under these licenses shall not be affected. In contrast, some copyleft licenses, such as GPL v2, GPL v3, require that the source code be made available to the user, as of request, the software be licensed royalty-free and the user has the freedom to modify and create derivative works. The GPL licensed software, unless exceptions and permissions apply, is likely to fall under the group of licenses, referred to as CLT.

These considerations shall be sufficient to allow the Parties to assess whether the open source software which they use and/or introduce in EURECA contains one or more criteria of the Controlled License Terms. The Parties shall also be in a state to evaluate the chances of getting approval of the Parties for the like work.

3.3.7.2 Use of external open source software

It is envisaged that some software and ICT tools in EURECA will be developed based on the state of the art in the medical research domain.

Among the open source solutions that may be relevant for EURECA are Unified Medical Language System[339], Web Service Modeling Ontology[340], Web-Service Semantics-WSDL-S[341], Microsoft Health Vault [342], to name a few. Tolven[343] is written in

[339] See for more information: http://www.nlm.nih.gov/research/umls/.

[340] See for more information: http://www.wsmo.org/.

[341] See for more information: http://www.w3.org/2005/04/FSWS/Submissions/17/WSDL-S.htm.

[342] See for more information: https://www.healthvault.com/de/de.

Java and is licensed under the GNU Lesser General Public License (LGPL) v 2.1[344], which is an open source license. Apart from Tolven, a number of ICT tools and solutions in EURECA will be based on or developed from the open source licensed codes which are already developed. "*Given the nature of the open development model, it is frequently unnecessary to create a new program from scratch. Whatever the program´s function, it is likely that someone, somewhere has done something similar*"[345].

With respect to using external code for building software in EURECA, the license terms of the original code shall be considered. Permissive copyright licenses, like BSD License and MIT License, allow distribution of the derivative works on the terms at discretion of the licensee, including proprietary licenses, require, however, that their license terms, as applicable to the original code, be fulfilled. Copyleft licenses, such as Mozilla Public License and GPLx require that distribution of the derivatives be under the terms of the licensed code, e.g. GPL itself.

Mere use of the program under its intended purpose or as a tool for writing as program (e.g. making calculations) are outside the license scope:

"Activities other than copying, distribution and modification are not covered by this License; they are outside its scope. The act of running the Program is not restricted, and the output from the Program is covered only if its contents constitute a work based on the Program (independent of having been made by running the Program). Whether that is true depends on what the Program does"[346].

Hence, it is through modification and distribution of the original GPL covered program that "*GPL comes into effect*"[347].

Another issue with open source software is that "*Open source doesn't just mean access to the source code*"[348]. Open source software is made available for use under specific license terms. By performing acts of modification and distribution of the original program or derivatives from it, a user indicates acceptance of the license and is bound by the license. As Section 5 GPL v2 provides: "*by modifying or distributing the Program (or any work based on the Program), you indicate your acceptance of this License to do so, and all its terms and conditions for copying, distributing or modifying the Program or works based on it".*

---

[343] See for more information: http://home.tolven.org/.

[344] See for more information: http://sourceforge.net/p/tolven/code/11/#diff-1.

[345] Laurent, supra, p. 174.

[346] Section 0 GPL v2.

[347] Laurent, supra, p. 151.

[348] Open Source Initiative, The Open Source Definition, available at: http://opensource.org/osd.

By modifying and distributing GPL covered programs or programs based on a GPL covered program in breach of the GPL license terms, the user looses the rights licensed to him[349].

Permissive copyright licenses do not contain such a provision. Although the standard license requirements: to preserve the copyright and license notices with disclaimers seem to be simple to obey, however, distribution of derivative works in breach of those license terms "*may significantly compromise the violator´s ability to enforce its own copyright, with potentially dire consequences*"[350].

Similar legal consequences can arise when software that uses open source licensed code is distributed in breach of the licenses attached to the used code[351].

The Parties are more than expected to show some degree of diligence with respect to using the open source software and complying with the license terms thereof. The license applicable to the software in question is most likely to be found in the source code, or rather in the copyright files relating to particular modules, or copyright inventory or directory for the software as a whole[352].

Shall a Party reveal that it is "*unable because of third party rights to grant Access Rights which it reasonably believes that another Party will require, it will promptly notify such other Party (…)"* and, if possible, before signing the agreement with the requesting Party (Article 4.2.5 Paragraph 1 CA). By doing so, the Parties are made aware and may agree that such work "*may be used to develop the Foreground (…) and that Access Rights to such Foreground shall be subject to the terms and conditions of the"* license applicable to it (Article 4.2.5 Paragraph 2 CA). For instance, use of source vocabularies of Unified Medical Language System (UMLS) is agreed for use in the Project under the UMLS License[353].

3.3.7.3 License and compatibility issues

There are approximately 70 open source licenses[354] available. The licenses are frequently similar in substance (e.g. permissive versus copyleft licenses), however vary in detail and may have terms incompatible with other licenses in some respect.

---

[349] Section 4 GPL v2; Section 8 GPL v3.

[350] Laurent, supra, p. 156.

[351] Ibid, p. 158.

[352] Software Freedom Law Center, Publications, Maintaining Permissive-Licensed Files in a GPL-Licensed Project: Guidelines for Developers, available at http://www.softwarefreedom.org.

[353] Article 4.25 CA, License Agreement for Use of the UMLS Metathesaurus: https://uts.nlm.nih.gov/help/license/LicenseAgreement.pdf.

[354] See for a list The Open Source Initiative, Licenses by Name, available at: http://opensource.org/licenses/alphabetical.

For instance, there is a requirement that code licensed under a particular license cannot be used with a code licensed under another license. This license incompatibility causes problems by development of software where the source codes under different licenses are merged and the FOSS code is *"balkanised"*[355]. Although there are a number of solutions and services available which deal with license incompatibility (e.g. Koders.com by Black Duck Software[356]), "*it is an ongoing issue"*[357].

License incompatibility can be explained as follows. In order to combine two programs (or substantial parts of them) into a larger work, permission to use both programs in this way is needed. *"If the two programs' licenses permit this, they are compatible. If there is no way to satisfy both licenses at once, they are incompatible"*[358]. Distribution or modification of programs, including incompatibly licensed code, will result in copyright infringement[359].

If a work is licensed under a proprietary basis, the code, even if source code is revealed, cannot, as a rule, be combined with a code of another license (except through special exceptions, permissions or cross-licensing)[360]. The user who obtained software under a typical end-user license has no other rights than to use the software under its intended purpose. A combination of two programs under proprietary licenses, even if they are the same license, cannot be modified or distributed together without violating the license[361].

Permissive copyright licenses are compatible with each other, so that a BSD licensed program may be combined with a MIT licensed program and the combination may be released under a proprietary basis. The BSD-2-Clause License would require that the copyright notice, the license terms and the disclaimer be provided along with the code; the MIT License would require that copyright and permission notices be included; the proprietary license applicable to the combination may contain additional conditions[362].

---

[355] Rowland, supra, p.421.

[356] Black Duck, Ohloh Code, available at: www.koders.com is a source code engine that limits the scope search to certain licenses.

[357] Rowland, supra p.421.

[358] Free Software Foundation, Frequently Asked Questions about the GNU Licenses, available at: https://gnu.org/licenses/gpl-faq.html#WhatIsCompatible.

[359] Laurent, supra, p.159.

[360] Ibid, p.160.

[361] Ibid.

[362] Laurent, supra, p.161.

The Free and Revised BSD and MIT Licenses are compatible with GPL[363]. Apache License v.2 is considered to be compatible with GPL v3. However, "*GPLv3 software cannot be included in Apache projects. The licenses are incompatible in one direction only*"[364].

The license compatibility with GPL licensed code may be checked via: https://www.gnu.org/licenses/license-list.en.html.

Beyond these general observations and without knowing the exact licenses and technical interactions and development tree at hand, it is difficult, if not impossible, to give specific legal advice as to what licenses are compatible.

Open source licenses are based on templates but are subject to variations on practice. Most open source licenses are written by the programmers themselves. Hence, diligence on part of the programmers, who combine the codes and are conversant in the software development domain, is required.

3.3.7.4 Conclusions

Software, ICT tools and other solutions developed in EURECA may be protected under the copyright law under the patent law and to some extent under the legal regime of know-how, if the respective criteria of protection are fulfilled. The scope, perspectives, terms and rights, which the Parties wish to protect, shall be chosen by the Parties. The options of protection shall be evaluated by considering the object and rights to be protected and the expected ways of exploitation. The provisions laid down in the CA that govern Access Rights to Software can be deemed as sufficient so that the Access Rights in software, either for execution of the Project, or for Use, may be deemed enforceable. The Parties are expected to show diligence when they use open source software and are expected to respect the license terms.

3.3.8 Licensing solution for EURECA

EURECA follows an open source commitment. It is envisaged that software, generated by the Project, if possible, shall be released "open source"[365]. As was established during the session of WP 7 in the Project meeting, which took place in Brussels, June 2014, no licensing decision as to under what license the Project software will be released has been taken so far. However some of the Project parties, e.g. MAASTRO and VUA, declared that customarily they use the Apache License Version 2 (Apache v2) [366].

---

[363] Free Software Foundation, Various Licenses and Comments about Them, available at https://www.gnu.org/licenses/license-list.en.html.

[364] The Apache Software Foundation, Apache License v2.0 and GPL Compatibility, available at http://www.apache.org/licenses/GPL-compatibility.html.

[365] Article 4.2.73 CA.

[366] E-Mail [FP7-EURECA-Board] software under Apache 2.0 by Annette ten Teije of 26 June 2014.

We support this licensing decision. The reasons why Apache v2 can be seen as suitable for use are as follows.

3.3.8.1 Open source license Apache License Version 2.0

Apache License, Version 2.0, is a certified open source license[367]. It is a classic open source license, widely deployed in many open source projects. For instance, Apache HTTP server, "*the most popular web server on the Internet since April 1996*"[368], is licensed under Apache v2[369]. Apache license is used and suits well ICT projects which start as research projects with the goal to explore the technology and expect to expand into commercial applications, once the research ideas have proven to be successful[370].

Apache v2 is a classic open source license with non-restrictive terms. As do the other permissive copyright licenses, it allows Apache licensed code to be used both in software provided for free and in proprietary software distributions. It does not require that *"open source versions of the code be distributed"*[371]. The Apache licensed source code can go closed. It may be a reasonable option when commercial distribution of EURECA services to pharmaceutical sector may come into question.

Apache is a license with strong branding. It does not allow use of marks and names of the software developers for promotion of other software products based on Apache licensed code[372]. Adherence to communication standards, such as HTTP protocols, led Apache communication software to the dominant position on the market of standards compliant web servers[373].

3.3.8.2 Apache v2 license requirements

Apache v2 allows use of the software code in a wide variety of ways as long as the Apache license requirements are complied with.

The Apache v2 license requirements for distribution are stated in Section 4. Apache v2 allows modifying and distributing original programs and derivatives *"in any medium, with or without modifications, and in Source or Object form"*[374]. The software developer may exercise these rights as long as he does the following: identifies changes and

[367] OSI, Apache License, Version 2.0, available at: http://opensource.org/licenses/Apache-2.0.

[368] ASF, HTTP Server Project, available at: http://httpd.apache.org/.

[369] ASF, ASF Source Header and Copyright Notice Policy, httpd project NOTICE example, available at: http://www.apache.org/licenses/example-NOTICE.txt.

[370] Laurent, supra, p. 20.

[371] Ibid, p.14.

[372] Section 6 Apache v2.

[373] Laurent, supra, p.32.

[374] Section 4 Paragraph 1 Apache v2.

contributor of changes; preserves copyright, attribution notices and other license notices attached to the original code; provides copy of the license along with the code.

The software developers are allowed to add their own copyright statements and distribute software under different license terms upon condition, however, that by using the Apache licensed code they fulfill the requirements, stated above[375].

3.3.8.3 Apache v2 and patent rights

Grant of the patent license and patent termination clause of Apache v2 suits interests of EURECA too, since EURECA seeks to protect the Project outcomes by patents[376].

Grant of patent license from the contributors to the downstream licensees is provided in Section 3. By licensing software under Apache v2 each contributor "*grants (…) a perpetual, worldwide, non-exclusive, no-charge, royalty-free, irrevocable (except as stated in this section) patent license to make, have made, use, offer to sell, sell, import, and otherwise transfer the Work*"[377]. The patent license encompasses only the claims which are necessary so that the licensed program be used in a legally compliant way.

By the same clause the contributors of Apache software are protected from being sued for patent infringement. Shall any licensee file a patent action against any contributor on the basis that use of the Apache software infringes on the patent, the patent licenses granted to that licensee "*shall terminate as of the date such litigation is filed*"[378].

The patent termination clause is a reason why Apache v2 is advised. Although patent termination clause *"doesn't make the software immune to threats from patents, but it does prevent patent holders from setting up a 'bait and switch' where they release the software under free terms then require recipients to agree to nonfree terms in a patent license."*[379]

3.3.8.4 Apache v2 and license compatibility

Apache v2 belongs to a category of permissive copyright licenses with flexible terms. Flexibility makes it "*compatible with almost every form of open source license.*"[380]

The main requirements which software shall satisfy to be included in the Apache projects are as follows:

---

[375] Section 4 Last Paragraph Apache v2.

[376] DoW, WP 10, T. 10.4.

[377] Section 3 Apache v2.

[378] Id.

[379] FSF, How to choose a license for your own work, available at: https://www.gnu.org/licenses/license-recommendations.html.

[380] Laurent, supra, p. 14.

- *"The license must meet the Open Source Definition.*
- *The license must not place restrictions on the distribution of independent works that simply use or contain the covered work.*
- *The license must not place restrictions on the distribution of larger works, other than to require that the covered component still complies with the conditions of its license"*[381].

Apache v2 software may incorporate and be built upon codes licensed under permissive licenses. Such licenses include: MIT, Revised BSD License (without endorsement clause), Dedication and other licenses, "*considered to be similar in terms to the Apache License 2.0"* may be included in the Apache projects[382].

Programs under "weak copyleft" licenses, such as Eclipse Public License, Version 1.0, may also be included in Apache projects, provided inclusion is made as the "weak copyleft" license requires. Normally, such programs and associated licenses shall be labeled, the user shall be directed to get the reciprocally-licensed source. For that the URL of the home product may be provided[383].

GPL covered codes, including GPL v2, GPL v3, GPL with exceptions, AGPL, and also LGPL are not allowed to be used in the Apache software[384]. On the other hand, use of GPL licensed tool[385] for writing Apache software or running Apache applications on GPL licensed platforms, like Linux, is allowed[386].

Also, whereas GPL licensed programs may not be included into Apache software, Apache programs may well be used in projects released under GPL v3[387]. The FSF recognizes Apache v2 as compatible with GPL v3[388]. This, however, does not apply to GPL v2.

Because of license flexibility Apache software may be used in a number of other research projects which are released under other open source licenses, including GPL

---

[381] ASF, ASF Legal Previously Asked Questions, available at: http://www.apache.org/legal/resolved.html.

[382] ASF, ASF Legal Previously Asked Questions, available at: http://www.apache.org/legal/resolved.html.

[383] Ibid, How should so-called "Weak Copyleft" Licenses be handled?

[384] Ibid, Which licenses may NOT be included within Apache products?

[385] Ibid, Can Apache projects rely on components under prohibited licenses?

[386] Ibid, Does it matter what platform an Apache product is created to work with?

[387] ASF, Apache License v2.0 and GPL Compatibility, available at: http://www.apache.org/licenses/GPL-compatibility.html.

[388] FSF, Various Licenses and Comments about Them, available at: http://www.gnu.org/licenses/license-list.en.html.

v3. This license compatibility serves interests of EURECA. Use of the Project results for further research and development is possible.

3.3.8.5 Exploitation options

Software licensed under Apache v2 may be distributed both for free and on commercial basis. Section 4 Last Paragraph allows to "*provide additional or different license terms and conditions for use, reproduction, or distribution of Your modifications, or for any such Derivative Works as a whole".* This makes licensing of Apache software on proprietary basis possible, provided the Apache code remains under Apache and Apache license terms are complied with. Dual licensing of Apache software may also be considered, e.g. release under Apache for R&D, and release on proprietary basis into commercial exploitation.

Another exploitation option might be offer of the warranty protection or maintenance servicing for a fee. Under Section 9 Apache v2 acceptance of additional warranty and liability as well as acceptance of "*support, warranty, indemnity, or other liability obligations and/or rights consistent with this License"* for a fee are allowed. What is to be borne in mind is that by accepting such an additional warranty the licensor assumes warranty for the software package as a whole, including third party contributions. The contributors who submitted their parts "as is" upon disclaiming any warranty and liability shall be kept harmless. By assuming additional warranty such licensor agrees *"to indemnify, defend, and hold each Contributor harmless for any liability incurred by, or claims*" by default[389].

Another important issue for exploitation is that Apache v2 does not allow use of the names or trade names of the licensors for promotional purposes[390]. The copyright and other attribution notices may only be used to identify origin of the program, as the license requires[391].

Redistribution of Apache licensed software without proper attribution, use of the names and marks of the contributors, including the Apache Software Foundation, in a way which would imply that those contributors endorse such software distribution are forbidden[392].

3.3.8.6 Conclusions

From the above can be concluded that licensing EURECA software under Apache License Version 2.0 would allow EURECA to fulfill its general open source commitment. It will also serve interests of the Project partners to exploit their software on commercial basis (upon condition that by doing so they comply with the distribution

[389] Section 9 Sentence 2 Apache v2.

[390] Section 6 Apache v2.

[391] Ibid.

[392] ASF, Apache License and Distribution FAQ, available at: http://www.apache.org/foundation/license-faq.html#WhatDoesItMEA.

terms, as Apache license requires). Apache license is an optimal option for research projects with the perspective of commercialization.

Adherence to standards, patent grants and patent termination clause may also be suitable for the Project parties and protect them and further researchers from being sued for patent infringement.

Another major positive aspect of Apache v2 is its compatibility with a wide range of open source licenses. License compatibility of Apache v2 makes it attractive for research projects which envisage re-use and enhancement of project results by and for the benefit of open source research community, as EURECA does.

4 Summary

EURECA uses and produces a number of tools that qualify for protection as intellectual property in the broad sense. This Deliverable focused on the intellectual property rights these tools may enjoy outside the EURECA consortium, i.e. beyond the consortium-internal protection afforded through the CA and other legal instruments that are EURECA-specific.

This Deliverable identified and analyzed three main categories of tools: patient data, repositories (databases) and software. Each tool enjoys its own type of legal protection.

Patient data can be protected as undisclosed information as long as it is secret, i.e. not generally known to relevant circles, has commercial value due this secrecy, and steps are taken to keep it secret. As such, the rightholders can generally prevent the data being used by others without their consent.

Repositories that are databases in a legal sense, i.e. collections of data arranged systematically where the data is individually accessible, may be protected either by copyright if the database is the result of a creative effort, or by the *sui generis* database right if a substantial investment was made to obtain the contents. The protection afforded by these two rights is different, but can be generalized as the rightholder being able to restrict use of the database.

Software and software-related outcomes generated by EURECA may be protected by copyright, patent and know how, as well as through license agreements. The type of protection depends on the exact nature of the software/software-related outcome.

Copyright protects the expression of an idea, patents the functionality and certain inventive methods and CII, and know how the proprietary and undisclosed source code of software.

Software may also be distributed under certain licenses that restrict its use or create a general framework for its use that must be adhered to. An example of a suitable license is Apache License Version 2.0.