



## Deliverable No. 4.2

# Initial analysis of the copyright-related legal requirements for the sharing of data

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**ABSTRACT:**

This deliverable is an initial investigation into the Intellectual Property Right (IPR) related issues in the CHIC project, and contains an examination of these issues as they arise both during the development of the infrastructure and future exploitation of the CHIC integrative models (hypermodels). This report covers different aspects and sources such as copyright of computer programs, database right, patent, licenses, as well as the use of background and foreground in the project.

**KEYWORD LIST:**

Model, hypermodel, copyright, patent, idea, author, licences, copyleft, computer program, software, annotations, manual, databases, data repositories

<sup>1</sup> R=Report, P=Prototype, D=Demonstrator, O=Other

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**List of contributors**

- Nikolaus Forgó, LUH
- Iheanyi Nwankwo, LUH
- Marc Stauch, LUH
- Johannes von Zastrow, LUH

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## 1 Executive Summary

The CHIC project aims at developing cutting edge ICT tools, services and secure infrastructure to foster the development of elaborate and reusable integrative models (hypermodels) in the field of cancer diagnosis and treatment, as well as larger repositories so as to demonstrate benefits of having both the multiscale data and the corresponding models readily available in the VPH domain. This deliverable addresses potential intellectual property right (IPR) issues that may arise during the development of the CHIC tools and at exploitation. As researchers are constantly concerned about the possible loss of economical and scientific interest as a consequence of sharing their creativity, the analysis centres on which rights are likely to be generated and subsist per se, as well as who owns the relevant rights; it considers both the materials brought to, and those developed in, the project (as background and foreground, respectively).

Three main areas are focused on – the potential application of copyright and database right to computer software and/or virtual products, and data collections respectively. As stated, consideration is also given to the ownership questions, particularly in relation to copyright in respect of derivative and/or collective works. Subsequently, an analysis of the compatibility of licensing terms of inbound components (whether as open source or proprietary licenses), is provided as well as of the effect of any incompatibility on the exploitation of the foreground.

In the final analysis, copyright is seen as the most viable option for the protection of the foreground generated in the project. However, as the project is still at an early stage, this framework will be reviewed, and updated when a concrete design of the infrastructure has been iterated and implemented, so that it is clearer in detail how the components and models will interoperate and function as a whole in concrete circumstances.

## 2 Introduction

This Deliverable aims to evaluate the legal requirements relating to the use and development of models, hypermodels and databases within the CHIC project.

These terms will form the starting point for all further investigation. As will appear, the status and protectability of models, representing an idea combined within hypermodels and linking to the CHIC VPH toolkit, raise various legal issues in the field of Intellectual Property Law. Different IPR regimes are potentially implicated, that will be subject to ongoing detailed investigation in the present deliverable as well as in future deliverables, notably D4.3.1 (M14) and D4.3.2 (M42) as the project progresses. Potentially IPR issues may arise and cover different aspects of the CHIC work, albeit some parts might fall outside the scope of any IPR. In this regard, two key issues will be distinguished and considered in turn:

- (i) the need to determine what IP rights (may) exist in the relevant materials and if so who owns them; and
- (ii) the need to determine how these rights should/must be dealt with by the relevant individual partners and/or the CHIC consortium.

These issues themselves arise at two distinct temporal stages:

- (1) Building the CHIC ‘product’ – here issue (i) relates to the question of which partners (and/or other third parties) have relevant IP in the stock of components/materials brought to CHIC to be used within the project [i.e. the project background]; and issue (ii) concerns the question (insofar as an IP right is held by a given partner), how that partner may/must deal with the rights vis à vis other partners during the project. This would cover e.g. the need for cross licensing between partners in order for project goals to succeed. Where there are third party IP rights in a given component, then there is also the issue of what the relevant contributing partner and/or consortium may need to do to be able to use that component within the CHIC project;
- (2) Exploiting the CHIC product- here issue (i) turns on nature of the product(s) generated within and by the project – is this subject to IPR at all, and if so what kind? If so, who has the rights in such foreground – the individual partners (individually/jointly) or the consortium or third parties as well? This will turn also on the question of whether the relevant product is a joint work, a collective work, a derivative work, etc. The answer will also have an impact on issue (ii), which here concerns appropriate/mandatory models the partners/consortium should adopt for the CHIC product’s exploitation/onward licensing.

This WP4 Deliverable is to be seen as providing an initial analysis only, and will be therefore extended at a later stage, including – still at an early point within the overall lifetime of the CHIC project – in Deliverable D4.3.1, to be submitted in M14. Moreover an advance in technical understanding and potential opening up of other data applications is to be expected throughout the project’s progress that will substantiate the need for ongoing legal advice. Finally, an assessment will be provided in how far the existing IP-regime fosters or hinders the development of hypermodels in the ICT for health-arena.

### 3 Structure of document

The deliverable describes the IPR related issues by the results of the CHIC project.

The structure of the remainder of the deliverable is divided into four main parts. First Chapter 4 summarizes LUH's current factual understanding concerning the use and implementation of (component-)models and hypermodels. This understanding is grounded in the DOW as a starting point, but additional information from all relevant partners has also been collected concerning the development, use and implementation of models and other components of the hypermodel. Thereafter Chapter 5 provides an introduction and overview of the key IP regimes that potentially apply to intellectual digital works of the kind under construction in CHIC. Most prominently copyright law will be looked at, which at least in Europe is seen (following the Software Directive – originally from 1991) as the preferential method for protecting IP of computer programs. However attention is also given to the EU database right, knowhow, and to patent law. In each case, the legal rules are considered with reference to their likely application to the materials to be used and developed in CHIC, in order decide which mode of protection is likely to prove most promising.

Chapter 6, which follows, looks further at the complex questions of IPR ownership in respect of composite and/or derivative works (which include most software). Lastly, Chapter 7 examines models for the onward exploitation of materials developed in CHIC, in terms of the use and transfer of relevant IPR through an appropriate licensing regime. In particular different standard licences are detailed and analyzed in respect of their possible compatibility as regards the amalgamation of diverse software components. A critical aspect will be to ascertain the scope of a given IPR and its license, in case of incompatibilities. Solutions may differ, according to whether the rightholder is within the consortium itself or outside in case of a possible dual licensing. As part of the conclusions (set out in Chapter 8) an initial approach for the project to follow, based on the preliminary results of the deliverable, will be suggested.

## 4 Description and use of models in CHIC

From a general understanding, models represent ideas, and in mathematical terms, they mean methods of simulating real-life situations with mathematical equations to forecast their future behaviour.<sup>3</sup> In the context of CHIC, such ideas summarily concern possible explanations of cancer progression and response to treatment and promote a model for predicting real-life situations of cancer progression and response to treatment using algorithm, data and computer software.<sup>4</sup> CHIC envisages the possible integration of various multiscale models as described in D2.2:

**Atomic models:** models that deal with the interactions of atoms such as during drug-protein interactions.

**Elementary Model:** a model that has been designed, implemented (and possibly tested) to work as a single unit, regardless if it is a single-scale, single biological process or multi-scale/biological process model.

**Hypomodel or Component Model:** a model that is not composed of other models. Several hypomodels or component models can be linked to form a hypermodel.

**Hypermodel or Composite Model:** a composition of component models. Even hypermodels themselves can serve as component models for other hypermodels.<sup>5</sup>

At the developmental stage of the project, a series of adaptations will be made on existing models, where for instance, such models will be “decomposed into their elementary component models and re-created” according to the needs of the project.<sup>6</sup> Apart from adapting existing models, new models will also be developed by modellers in the project.<sup>7</sup> Furthermore, relevant models that are not yet transformed into computer program, will be transposed into code, and stored in the CHIC model repositories.<sup>8</sup> Amalgamations of hypermodels – combinations of hypo-models in which the output of one hypomodel forms the input of another, will also be an integral part of the project.<sup>9</sup> This will also involve

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<sup>3</sup> <http://www.businessdictionary.com/definition/mathematical-model.html>

<sup>4</sup> See CHIC Deliverable D6.1.

<sup>5</sup> CHIC Deliverable D2.2, (draft v0.8), p. 13, 19

<sup>6</sup> DOW CHIC, WP6, p. 24.

<sup>7</sup> See also DOW CHIC, WP6, p. 25, SubTask 6.4.c.

<sup>8</sup> DOW CHIC, WP6, p. 23.

<sup>9</sup> CHIC deliverable D2.2 (draft v0.8), p. 10.

the development of a “linker”, which for interoperability purposes, interconnects the various models in order to achieve the desired results<sup>10</sup>.

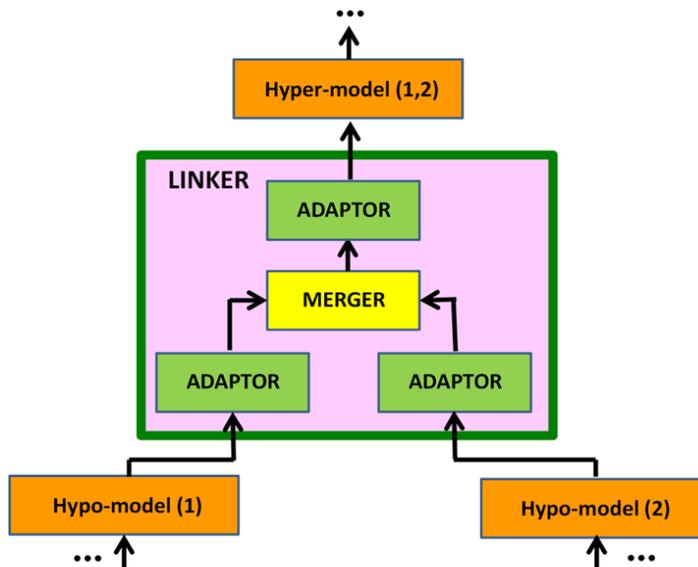


Figure 1: Cancer hypermodelling architecture showing the possible interaction of models with other tools.<sup>11</sup>

#### 4.1 Nature of models used/developed in the project

As indicated above, two broad categories of models will be used in CHIC – currently existing models, and new models to be developed by modellers in the consortium.

For relevant existing models in the VPH domain that are merely mathematical in nature (and could even be interpreted or applied with no aid of computers), the aim of CHIC is to adapt or transform these models, including coding them into software (where they are not already in such forms)<sup>12</sup>. This will be addressed by the “software layer” of the project<sup>13</sup>. In the end, a VPH-toolkit will be developed, where several models are combined with the aim of getting more detailed and accurate predictions about new experiments. This combination/amalgamation is done by computer tools and services to be developed in the project based on open standards.

<sup>10</sup> See also DOW CHIC, WP5, p. 20.

<sup>11</sup> See CHIC project summary presentation for the 1<sup>st</sup> review meeting.

<sup>12</sup> See CHIC deliverable D2.2 (draft v0.8), p. 10. Apart from the existing models that will be used in CHIC, some other models will be developed from the scratch for the purposes of the project.

<sup>13</sup> See CHIC deliverable D2.2 (draft v0.8), p. 9.

The models and tools developed in the project will be as granular and modular as possible to allow easy re-use of the tools. In this respect, existing tools that fit into the purposes of the project will be reused to avoid building models and tools from the scratch<sup>14</sup>. However, in order to achieve the desired interoperability, the project will as noted add necessary tools such as the “linker”, (see figure 1) to facilitate the interaction of all component-models: this aspect will be addressed by the engineering layer of the project.<sup>15</sup> The intention is that by combining component models into hypermodels, and with input data from patients, a hypermodel would be able to simulate all biological processes that are considered to be of relevance for cancer development and treatment. As a result, it is hoped that it will be possible to make prognosis of cancer through simulation.<sup>16</sup>

The developed infrastructure will consist “primarily of a hypermodeling editor and a hypermodel execution environment, an infrastructure for semantic metadata management, a hypermodel repository, a hypermodel-driven clinical data repository and an in silico trial repository for the storage of executed simulations scenarios.”<sup>17</sup> These resources will be accessed through an end user portal, and the services offered by the infrastructure could be utilized as software as a service.<sup>18 19</sup>

## 4.2 Generating models and other tools and associated copyright

There are considerably over 50 cancer models, already existing or being developed, refined or adapted by the CHIC cancer modeling partners.<sup>20</sup> Detailed outlines of the models have been presented in D6.1.

CHIC Partner	Using existing models	Developing new model
ICCS	X	X
OXFD	X	

<sup>14</sup> CHIC deliverable D2.2 (draft v0.8), p. 2.

<sup>15</sup> See CHIC deliverable D2.2 (draft v0.8), 10; DOW CHIC Part B, B1.1.1.3, p. 5, referred to as pre-processing tools.

<sup>16</sup> CHIC deliverable D2.2 (draft v0.8), p. 16.

<sup>17</sup> DOW CHIC Abstract, p. 3; DOW CHIC Part B, B1.1.1.2b, p. 5.

<sup>18</sup> CHIC deliverable D10.1.

<sup>19</sup> CHIC deliverable D2.2 (draft v0.8), pp. 7, 8.

<sup>20</sup> CHIC deliverable D6.1.

UPENN	X	X
UBERN	X	
FORTH	X	
UNITO	X	

As will be shown in detail in the next chapter, a general rule is that ideas are not subject of copyright protection; only the expression of such ideas are protected.<sup>21</sup> Figure 2 below shows a possible progression of a model; while ideas are not protected, their expression in form of a publication or computer program is protected once there is originality in the expression. The amalgamation of models as well will enjoy protection if the integrative process itself involves an original expression. Further discussion on these issues will be provided in the next chapter.

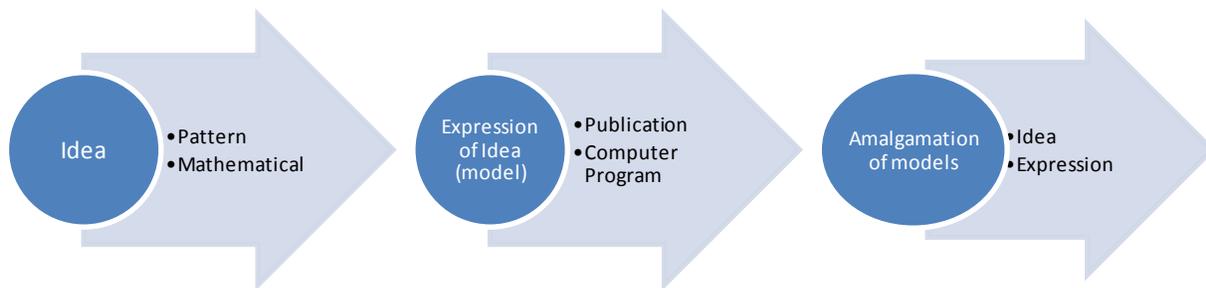


Figure 2: Possible progression of a model from copyright perspective. Each progression may or may not be protected by copyright.

<sup>21</sup> See chapter 5 of this deliverable.

## 5 Subsistence of IPR in software and data and model amalgamation in CHIC

### 5.1 Introduction

This chapter will provide an overview of the key IP regimes applicable to the CHIC project and their overall purpose, requirements and effect. In each regime the detailed rules at national law level vary between countries, but for the purposes of this Deliverable, the focus will be on relevant EU provisions that in turn are based on international treaties, such as the Berne Convention<sup>22</sup> and WIPO Treaties.

In accordance with the Description of Work task description (T4.2), the principal attention will be given to copyright law, and its application in the context of the CHIC computer models developed and expressed in software; accordingly, the main focus will be upon copyright law as it applies to computer programs. However, as the use of the models is premised upon the use of data, including retrospective data in databases, and the establishment of linked data repositories, another focus will be on the sui generis database right in EU law. Moreover, in this regard, there will also be consideration of the (non-proprietary-based) legal protection applying to “confidential information” and “knowhow”. Lastly, as there has been an increasing tendency for computer software to be regarded as potentially subject to patent protection (to the extent it comprises part of a computer implemented invention (CII)), there is an examination of relevant patent law principles. In this respect we consider how far the patent registration route could serve in CHIC as a further or alternative option to reliance on copyright and/or the database right.

In the present Chapter the focus will be upon the potential IP rights from an ontological perspective, i.e. which rights are likely to be generated and subsist per se, in materials brought to and developed (as background and foreground, respectively) in the CHIC project. The regimes noted above are looked at, first in overview, and then with the focus on their potential application to the computer software, data and ideas constitutive of the models, tools, and repositories being developed in CHIC.

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<sup>22</sup> Berne Convention for the Protection of Literary and Artistic Works, 1979 as amended, available at [http://www.wipo.int/treaties/en/text.jsp?file\\_id=283698](http://www.wipo.int/treaties/en/text.jsp?file_id=283698).

## 5.2 Copyright

### 5.2.1 Overview

Copyright law is concerned with giving authors of creative works protection in their works. It does so by granting authors of such works ownership or property rights, which take into account the authors' material interests by giving them (in the first instance) the exclusive rights to deal with their work in a prescribed way, including to reproduce (copy), distribute to the public, or adapt the work. A notable feature (which indeed distinguishes copyright from most other types of intellectual property law protection, such as patents or trademarks) is that the protection of authors' rights stems simply from the act of creation; in particular it does not depend on or require any further formalities, such as registration or deposit of the work (as found, say, in patent law).

The modern system of copyright protection is anchored in a number of important international agreements, beginning with the signing of the Berne Convention for the Protection of Literary and Artistic Works, in 1886. The Berne Convention has been subject to various revisions since, but additional key treaties have also been agreed and ratified, notably the Universal Copyright Convention of 1952 (which is administered by UNESCO), and the 1994 Trade-Related Intellectual Property Aspects (TRIPS) Agreement. In addition the World Intellectual Property Organisation (WIPO) has promulgated international copyright law in two treaties from 1996, the WIPO Copyright Treaty (WCT)<sup>23</sup> and the WIPO Performances and Phonograms Treaty (WPPT)<sup>24</sup>. These treaties aim inter alia to provide adequate protection for creative works in the new digital environment.

Given the importance of copyright works for free trade, and the need for a harmonized level of protection so as to encourage their unhindered movement within the European single market, there have also been significant initiatives in copyright law at European Union level. These include the 'Copyright Directive' (sometimes also termed the InfoSoc Directive), 2001/29/EC on the harmonisation of certain aspects of copyright and related rights in the information society, as well as a Directive (2009/24/EC (re-enacting the earlier Directive 91/250/EC), with specific reference to copyright in relation to computer programs. The provisions of this 'Software Directive' will be considered further in detail in

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<sup>23</sup> See: WIPO Copyright Treaty, 1996, available at: [http://www.wipo.int/treaties/en/ip/wct/trtdocs\\_wo033.html](http://www.wipo.int/treaties/en/ip/wct/trtdocs_wo033.html).

<sup>24</sup> See: WIPO Performances and Phonograms Treaty, 1996, available at: [http://www.wipo.int/treaties/en/ip/wppt/trtdocs\\_wo034.html](http://www.wipo.int/treaties/en/ip/wppt/trtdocs_wo034.html).

part 5.2.2 below. That part also discusses the issue of copyright in databases, which has been addressed at EU level in the Database Directive 96/9/EC.

As noted, the effect of copyright law is to reserve certain rights to the author of the copyright in a work that enable the owner to exploit the work to the exclusion of others; these include primarily the right to copy, distribute, and/or adapt the work. The first of these, the right of reproduction, is arguably the most fundamental of such ‘economic’ rights, as copying is a precondition for most subsequent commercial uses. In this regard, reproduction has a wide meaning, and extends to all methods of copying a work, both present and future. Traditional examples are printing (copyright law is seen as having its inception with Gutenberg’s invention of the printing press in the fifteenth century) and photocopying of books or journal articles as well as the recording of music and films. More recently, given developments in digital technology, it has been widely recognized, and is reflected in international legal treaties (including the TRIPS agreement) that the digital storage of a work in an electronic medium amounts to reproducing it for the purposes of copyright law<sup>25</sup>. As regards the other key rights reserved in the first instance to a work’s author, that of distribution covers the putting copies of the work into circulation, while making an adaptation means modifying an existing work to produce a new work (i.e. a ‘derivative work’). As well as traditional modes of transformation, such as translating a novel from French to English<sup>26</sup>, or turning it into a theatrical play, this may also include modern, computer-based acts such as changing the arrangement of a software program or a database<sup>27</sup>. The adaptation right means that a person who wishes to undertake such activity must obtain the authorization (consent) of the holder of the copyright in the original work.

In addition to these key economic rights, the author is also invested with certain ‘moral rights’ in his creative work. The latter are connected to the person of the author, and continue to inhere in the author, even if the latter (as will generally be the case) has transferred the economic rights in the work to someone else in order to exploit it commercially. Indeed, a key feature of moral rights is that they are not assignable. The most important moral rights under both the Berne convention and WIPO treaties are

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<sup>25</sup> Recital 2 Directive 91/250/EEC.

<sup>26</sup> See: art 8 Berne Convention.

<sup>27</sup> Eisenmann, Harmut and Jautz Ulrich, *Grundriss Gewerblicher Rechtsschutz und Urheberrecht*, C.F Muller, 2009, p. 18.

to have the work attributed to the author as creator (attribution) and the right to object to injurious adaptations of the work into a derivative work (integrity)<sup>28</sup>.

As already suggested, copyright in a work will in most cases initially belong to the person who has created it, i.e. the author. However, there are some exceptions in relation to the economic rights to exploit the work, notably where the work is created by an employee in the course of his employment. In addition there are complex rules that apply where works are created by multiple authors, which vary both according to whether the work is divisible into discrete contributions and whether or not the authors were acting in concert. These rules, which are highly pertinent in relation to the collective enterprise of project work, as is the case in CHIC, will be considered in the following chapter (Chapter 6). It should be reiterated that ownership of the economic rights stemming from copyright may also be transferred in various ways, typically through contractual agreements, which may take form of assignment (where the first owner divests himself of the property altogether<sup>29</sup>) or by license (where he retains a reversionary interest). The issue of licensing the use of computer software is a complicated field, which has relevance to both the use of the background and exploitation of the foreground within the CHIC project; it is looked at in Chapter 7 below.

International conventions as well as national laws provide that copyright will subsist in ‘works of a literary, scientific or artistic nature’. In this regard, article 2(1) of the Berne Convention states that the expression “literary and artistic works” includes, “every production in the literary, scientific and artistic domain, whatever may be the mode or form of its expression”, and proceeds to give illustrative examples such as “books, pamphlets and other writings; lectures, addresses, sermons and other works of the same nature; dramatic or dramatico-musical works; ... cinematographic works; works of applied art; ... illustrations, maps, plans, sketches and three-dimensional works relative to geography, topography, architecture or science”. In the 1996 WIPO WCT Treaty it was provided by Article 4 that, “computer programs are protected as literary works within the meaning of Article 2 of the Berne Convention. Such protection applies to computer programs, whatever may be the mode or form of their expression”. In addition, under Article 5 WCT, it is stated that compilations of data (databases) in principle may also be subject to copyright protection.

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<sup>28</sup> E.g.: art. 6bis Berne Convention.

<sup>29</sup> In some jurisdictions transfer of the property is not possible, e.g. in Germany: § 29 Urheberrechtsgesetz.

At the same time, it is important to note two key qualifying conditions for a work to attract such protection. In the first place, a work has to be more than a mere idea: the ideas found in a work cannot be protected by copyright<sup>30</sup> (e.g. according Art. 2 (1) Berne Convention, Recital 11 2009/24/EC only the concrete expression enjoy protection under copyright) and may be used freely as part of the public domain that everyone may draw upon. Rather, what is protected as the intellectual capital of a particular author is the expression or tying down of a given idea in a particular form. This distinction (often termed the ‘ideas/expression dichotomy’) is at the heart of copyright law. In short, for copyright in a work to be infringed, the infringer must have copied the form in which the ideas were expressed. Secondly, to qualify for copyright protection, a work must be original. There is no international consensus as to what originality means, or universally agreed standards. Thus in common law countries courts require the display by the author of a certain degree of skill, labour and judgment for his or her work to be regarded as original (the so-called ‘sweat of the brow’ approach). In civil law countries, by contrast, courts require more: to count as original, the work - as well as displaying the straightforward application of skill, etc - should in some way reflect the individual personality of its creator. Even so, in such countries as well, it is accepted that quality, novelty, or artistic value are not relevant in assessing originality (i.e. a poorly executed painting attracts copyright in just the same way as an accomplished one). Nor does it matter whether a given work was created for utilitarian or higher cultural purposes. For software programs this threshold of originality is regarded as being somewhat lower still<sup>31</sup>.

Lastly, it should be noted that, though normally a person who deals in an unauthorised way with a copyright work, e.g. reproduces it (or a significant part of it) without the author’s consent, will infringe copyright, this is subject to the application of certain defences that the infringer may plead. The details of these defences (which recognise the public interest in being able to access and use copyright works for certain purposes) vary under different national systems. This includes as between different Member States in the EU: here Article 5 of the Copyright Directive gives individual states significant leeway, providing an exhaustive list of defences that states may choose (or not as the case may be) to recognise in their respective domestic legislation. A wide and well-known defence outside the EU context is the US legal concept of ‘fair use’, which gives courts discretion to find a given unauthorized dealing with a copyrighted work reasonable (and hence not infringing). Relevant factors for the judge to consider will be “the purpose and character of the use, including whether such use is of a commercial nature or is for non-profit educational purposes; the nature of the copyrighted work; the amount and substantiality of

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<sup>30</sup> WIPO Copyright Treaty (1996), Article 2.

<sup>31</sup> Eisenmann/Jautz, Grundriss Gewerblicher Rechtsschutz und Urheberrecht, 2009, p. 48.

the portion used in relation to the copyrighted work as a whole; and the effect of the use upon the potential market for or value of the copyrighted work”. This defence is also reflected to some extent in UK copyright law in the form of the defence of fair dealing<sup>32</sup>; however, it is not found in civilian law copyright legal system, where defences to copyright infringement are drawn more narrowly and specifically<sup>33</sup>.

## 5.2.2 Copyright in Software and (Compilations of) Data

As noted above in part 5.2.1., computer programs are recognized as eligible subject matter for copyright protection under the WIPO WCT Treaty. Similarly, Article 10 (1) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) stipulates, that “computer programs, whether in source or object code, shall be protected as literary works under the [Berne Convention]”. The relevant copyright may subsist both in the source code for the program (whatever the computer language used), and in the object code. Moreover, protection will apply not just to software in the narrow sense of application programs, but also to underlying computer operating systems. Here, the form the program is embodied in is irrelevant; it may be recorded on paper, stored on a CD, or stored in the memory of a computer. As was further noted, the European Union has implemented such protection at EU level in a dedicated directive, namely Directive 2009/24/EC, which is itself a consolidated and re-enacted version of the earlier Directive 91/250/EC.

Directive 2009/24/EC - the Software Directive, operates to harmonise many of the rules at member state level concerning the protection of computer programs. All member states have amended their IPR regulations according that Directive<sup>34</sup>. The Directive defines in its Article 1 (2) computer program as an “expression in any form”, and recital 7 states that computer programs mean, “Programs in any form, including those which are incorporated into hardware; whereas this term also includes preparatory work leading to the development of a computer program”. Excluded by Article 1(2) though, in line with the general ideas/expression dichotomy referred to in part 5.2.1 above, is the application of the Directive to the idea a computer program is based on as such. Here recital 11 of the Software Directive states that: “Whereas, for the avoidance of doubt, it has to be made clear that only the expression of a computer program is protected and that ideas and principles which underlie any element of a program, including

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<sup>32</sup> Copyright, Designs and Patent Act 1988, section 29.

<sup>33</sup> E.g.: § 53 Urheberrechtsgesetz.

<sup>34</sup> See Recital 6, Directive 91/250/EEC.

those which underlie its interfaces, are not protected by copyright under this Directive”. Recital 11 of the Directive goes on to add that: “Whereas, in accordance with this principle of copyright, to the extent that logic, algorithms and programming languages comprise ideas and principles, those ideas and principles are not protected under this Directive”. Here, the protection of an IPR in form of a copyright will cover only the implementation/realization *in concreto*. The Directive in its recital 15 uses the term “expression” for the concrete implementation of an idea covered by copyright. Under Article 1 (3) “a computer program shall be protected if it is original in the sense that it is the author’s own intellectual creation”<sup>35</sup>.

Generally speaking, the copyright protection accorded to computer programs may be seen as corresponding (including being subject to similar limitations and qualifications) to that enjoyed by other literary works. Notwithstanding this, however, the Software Directive acknowledges that in some respects computer programs cannot be straightforwardly analogised to other literary works. It does so by containing special provisions that exempt certain types of copying, essential for running and/or developing software from constituting the copyright infringement these would be if done with respect to ordinary (non-computer) literary works. Foremost among these exemptions are the rights of the lawful acquirer under Article 5 of the Directive to do things necessary in connection with the ordinary use of the program, including correcting bugs and making a back-up copy. He is also permitted to observe study or test the functioning of the program to determine the ideas and principles which underlie any element of the program without the agreement of the copyright-holder. In addition, under Article 6, it is permissible for the licensee or other lawful user of the program to copy the code of the program in the course of ‘decompiling’ it (i.e. reconvert object code back into original source code) for the purposes of securing interoperability between that software and other software components. Provided further that the information necessary to achieve interoperability is not otherwise readily available, such activity is in effect exempted from copyright restraints on policy grounds, so as to encourage a competitive market in software<sup>36</sup>.

More recently, in the case of *SAS Institute Inc vs. World Programming Ltd*, C-406/10<sup>37</sup>, the European Court of Justice addressed a further issue that can be regarded as distinctive to copyright in computer

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<sup>35</sup> As suggested in the text at n 30, the threshold for protection is low, reflecting the ease of copying but at the same time the economic interest in encouraging innovative computer programs.,.

<sup>36</sup> See recital 10 and 11 Directive 2001/29/EC.

<sup>37</sup> ECJ C-406/10, <http://curia.europa.eu/juris/document/document.jsf?text=&docid=122362&pageIndex=0&doclang=EN&mode=lst&dir=&occ=first&part=1&cid=16381>

programs (as opposed to any other type of literary work), namely the phenomenon of ‘non-literal copying’. The latter arises where a third party, though using completely different underlying source and object code, sets out to recreate the effect of some software, in terms of its surface ‘look and feel’ (as perceived by the software user). The question for the Court, in terms of the ideas/expression dichotomy underpinning copyright law, was whether such a third party work infringes the protected ‘expressive’ aspect of the original software, or ‘look and feel’ is instead an aspect of the non-protected idea underlying the software. This question had previously given rise to a complex and often inconsistent case law both in Europe, and especially the US. However, in its decision in the *SAS Institute* case the ECJ opted for a relatively straightforward approach, interpreting Article 1 (2) of the Software Directive as mandating such non-literal copying (and hence rejecting the claim of infringement). This approach may also be seen as consonant with underlying policy aims in terms of promoting healthy competition among software developers.

Under Article 2 (1) of the Copyright Directive 2001/29/EC, “the author of a computer program shall be the natural person or group of natural persons who has created the program or, where the legislation of the Member State permits, the legal person designated as the right-holder by the legislation”. In case a group of persons created a computer program jointly, “the exclusive rights shall be owned jointly”, as provided by Article 2 (2). An exemption mentioned in the Directive covers the situation in which a natural person works as an employee; here Article 1 (3) states: “where a computer program is created by an employee in the execution of his duties or following the instructions given by his employer, the employer shall be entitled to exercise all economic rights in the program so created, unless otherwise provides by contract”. We shall return to the question of ownership in computer programs in more detail in the next chapter.

Beyond the issue of software, a further key issue to be considered concerns the potential protection under copyright of data and compilations of data (contained in a database or repository). First, as regards unprocessed ‘raw’ data, it is apparent that this, insofar as it simply records natural facts and/or observations of the same, will lack the element of creative expression necessary to attract the relevant protection by copyright law. The question of other possible legal protection for data per se is looked at further under part 5.3. However, at this point one may note that once individual data (data points) are ordered into a structured format, e.g. by being organised into a table, then copyright might potentially be argued relative to the effort expended in the ordering itself. At any rate this could be the case under the common law, with its ‘sweat of the brow’ approach. By contrast, traditionally at least, under the higher civilian standard, requiring some sign of the author’s personality, such an argument would be less

likely to succeed. This question should though now be considered in the light of the ECJ's 2011 judgment in the case of *Infopaq International A/S (C-5/08)*<sup>38</sup>, where the Court, applying the Copyright Directive appeared to endorse a relatively low (pan-European) threshold for fragmentary expressions to have the personality creativity necessary for copyright protection: it was sufficient that the author had some degree of free choice in the arrangement of the material. Admittedly that case concerned ordered sequences of words rather than the structured formatting of data per se; however, a key concern of the Court (in the spirit of the sweat of the brow doctrine) seems to have been to prevent free-riding for commercial advantage on the efforts of others, a concern that may apply equally in the latter situation.

It should be recalled that, under Article 5 of the 1996 WIPO WCT, it is also stated that compilations of data (databases) may attract copyright in their own right, insofar as they meet the necessary requirements of creativity and originality. Here, the European legislator has anticipated possible problems (in particular in civil law jurisdictions) in sometimes establishing the requisite personal creativity on the part of the compiler, by enacting a secondary form of sui generis IP protection for databases. This issue will be discussed further in part 5.3.1 below.

Concerning the annotations and description of models, it is questionable that they are covered by an IPR. The ECJ held in the already cited decision that “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.”<sup>39</sup>

By contrast, a written description of a computer program (in a user manual) may be covered by IPR. This will depend on, “whether the reproduction of those elements constitutes the reproduction of the expression of the intellectual creation of the author of the user manual for the computer program at issue in the main proceedings” and is to be decided in every single case by national courts.<sup>40</sup> Although there are few relevant cases in point, a decision by the (German) Bundesgerichtshof answered a similar question in 1992 already, finding copyright to cover drawings and pictures in a user manual alone. A decision concerning copyright in the user manual text was left open, with the court questioning its

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ECJ

C-5/08,

<http://curia.europa.eu/juris/document/document.jsf?text=&docid=72482&pageIndex=0&doclang=EN&mode=lst&dir=&occ=first&part=1&cid=16669><sup>39</sup> ECJ, *SAS Institute Inc vs. World Programming Ltd*, C-406/10, rec. 66.<sup>40</sup> ECJ, *SAS Institute Inc vs. World Programming Ltd*, C-406/10, rec. 68.

originality and referring the matter back to a court of lower instance<sup>41</sup>. In principle, though, the BGH was of the view that a user manual could be covered in cases of an original work.

### 5.2.3 Potential relevance to materials at issue in CHIC

As mentioned in chapter 4 already, one aspect of the CHIC project is the development of new and/or reuse of existing models and their amalgamation into hypermodels. These will be provided with an infrastructure to achieve interoperability both among themselves and with the further resources necessary to execute the models. This includes also the provision for linkage to specialised repositories and the need for annotations and meta-description of relevant materials and data.

There are various permutations that arise when considering the copyright that subsists in a complex work, such as that represented by the CHIC infrastructure. Indeed, the reality is that one is not dealing with a single work, but a composite work in which a bundle of many distinct copyrights and other IPR arise and subsist simultaneously. It appears at this stage (subject to further more detailed information becoming available in the course of ongoing iterations) that relevant individual CHIC partners will contribute their computer models (software, containing advanced algorithms that operate in conjunction with data inputted to generate – including the time-dimension- 3- and 4-D images) as well as other data and information. As discussed in part 5.2.2, both the source and object code written and used in the software itself constitute computer programs, which are treated as ‘literary works’ for purposes of copyright, and hence protectable subject to the requirements of originality and tangible expression.

Various aspects of the CHIC project outcome could be covered by copyrights. First of all the models and/or hypermodels, where constituted by and/or deploying original code, could be covered by IPR as a computer program. Copyright could in principle also extend to preparatory written drafts outlining the structure of a program (so far as this includes sufficient expressive detail to make the draft more than a mere ‘idea’, and involved significant skill and judgement ),<sup>42</sup> as well to the compilation of subroutines into a new program. In the latter case, to meet the originality requirement, the act of compiling must – as with other compilations – involve some exercise of original choice, rather than being dictated by

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<sup>41</sup> BGH, Urteil vom 10-10-1991 - I ZR 147/89 (Oldenburg), NJW 1992, pp. 689.

<sup>42</sup> See e.g. the UK High Court decisions in *Ibcos Computers v Barclays* [1994] FSR 275, and *Cantor Fitzgerald International v Tradition (UK) Ltd* [2000] RPC 95.

simple efficiency requirements.<sup>43</sup> Similarly, whether a description of a computer program is covered by IPR is a question, “whether the reproduction of those elements constitutes the reproduction of the expression of the intellectual creation of the author of the user manual for the computer program at issue in the main proceedings”. Such questions will be decided in each case by national courts, and by reference to the relevant individual circumstances.<sup>44</sup> Admittedly, as detailed above, the mere idea as such is not covered. In other words the logic of a program and algorithms are not protected under any copyright. Hence the models understood as an idea to explain a certain phenomenon is, because it lacks a form of expression, not subject to the rules of copyright. However, when a model is implemented in a piece of software, it will gain an expressive form: a computer program exists and its author obtains a copyright in the expression. As outlined above, the form of expression, whether written in source or object code, or indeed – for preparatory work – detailed notes or diagrams, does not matter. Similarly, any other elements of the CHIC infrastructure that contains original expressive material and/or computer code, including the underlying system used for running the components, will equally be subject to copyright protection. So too, as noted at the end of 5.2.2, would be original written user manuals/descriptions of different CHIC models facilitating future reuse.

Regarding data, in digitalised form, that is placed and stored in the CHIC repositories, and subsequently accessed and used as part of the execution of the hypo and hyper-models, it is possible too that these could be subject to copyright protection. It is true that, as noted earlier, raw data and ‘facts’ per se are not copyrightable, however, where effort, including a degree of originality is expended upon the way that datasets are presented and expressed, copyright could arise. Thus in the *Infopaq* case, the ECJ held that the arrangement of 12 words in a particular sequence attracted copyright. Another possibility is that the effort involved in compiling the data in the database could (subject to sufficient creativity by the person responsible) lead to copyright in the database itself as a creative compilation. Failing that, the (non-creative) effort and investment in gathering and verifying the data in the database may attract sui generis protection in the EU in accordance with the database right (under Directive 96/9/EC) – see further the discussion in part 5.3.1 below.

Part of the work to be envisaged within the CHIC project is, as detailed above, the annotation of data and models, to make them interoperable. Whether this annotation work is covered by any copyright is more questionable. The ECJ held in the *SAS Institute* case already cited that “the keywords, syntax, commands

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<sup>43</sup> See *Computer Associates International v Altai Inc.*, 982 F 2d 693 (1992), a US decision that has also proven influential in Europe.

<sup>44</sup> ECJ, *SAS Institute Inc vs. World Programming Ltd*, C-406/10, rec. 68.

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.”<sup>45</sup> In this regard, the annotation might be considered as a sort of keyword or syntax to perform software only, so it is more likely that this work is not protected as a “literary work”. The question of the status of meta-descriptions of a computer program and how to use it appears even more complex and controversial and is most probably to be decided on a case-by-case basis. The result will turn on whether the manual created within the CHIC project is deemed an “expression of the intellectual creation of the author of the user manual for the computer program” or not. At this initial stage it is apparent that this question in any event needs further clarification following a further factual assessment. By contrast, what seems clear is that the mere description of the standards of the program, e.g. the syntax or keywords described in a manual, are not protected by copyright.

### ***5.3 The database right and the protection of information***

#### **5.3.1 Overview**

A database may be defined as a compilation of data selected and arranged according to defined principles. In the case of an electronic database, the storage will occur in the memory of a computer system to which users are given access. Today, with the growing trend for information services to be made available electronically, often on-line, the protection of intellectual property in databases has become an important economic issue. Moreover, databases increasingly play a key role as components in the operation and exploitation of multimedia products. Databases are generally subject to two main forms of protection. First of all, as discussed in part 5.2.2, a database may be protected as an original intellectual creation by reason of the selection or arrangement of the information it contains. If such selection is creative, protection follows. In that case they are considered original databases, which are essentially subject to the general copyright rules. Protection in such a case inheres in the distinctive structure of the database, i.e. the ‘architecture’ provided by the author, and not the data or material itself. Third parties may therefore use the same or similar data; yet they must not (unless authorized) adopt the way in which the original database arranges them, or the same selection.

Secondly, however, some jurisdictions (including all EU Member States, following EU Harmonization) have provided for a secondary level of protection for databases in the form of a sui generis right, i.e. a

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<sup>45</sup> ECJ, SAS Institute Inc vs. World Programming Ltd, C-406/10, rec. 66.

discrete right that protects data bases for compilers of databases against extraction or re-utilization of the contents themselves. This reflects the fact that, as noted in part 5.3.1, many civilian law jurisdictions require some distinctive creative input, reflecting in some way the author's personality, as a condition for copyright protection. On this approach (in contrast, to the lower, common law 'sweat of the brow' approach, it may often be difficult to show sufficient creativity in compiling a given database to secure copyright. Accordingly, there is a need for secondary protection to ensure that (in the absence of copyright) compilers retain an incentive to create and compile databases: as EU Directive 96/9/EC (discussed below) notes it in its recital 7, "Whereas the making of databases requires the investment of considerable human, technical and financial resources while such databases can be copied or accessed at a fraction of the cost needed to design them independently". Accordingly, and in contrast to copyright in original databases, this form of protection will be awarded irrespective of whether or not the structure or selection shows creativity in itself or not. Instead, it is enough for the compiler to advert to the investment of time, money and effort to collect the data or other materials.

Within the EU the key provisions in relation to IP in databases (both in respect of copyright and the secondary, *sui generis* right) are set out in Directive 96/9/EC on the legal protection of databases (hereafter, 'the Database Directive'). The Directive defines a database in Article 1 (2) 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", and applies to databases, irrespective of their form (e.g. electronic or print media). However, under Article 1(3) it does not apply to the software used in the making or operation of the database (which are protected instead by the Software Directive; see the discussion in part 5.3.1) Nor, according to the terms of Article 3(2) of the Database Directive, will its protection extend to the contents of the database.

The Directive's protection of the structure of a database under copyright law is set out in Chapter II (articles 3-6) and essentially provides (in line with Article 6 of the Agreement on TRIPS) that copyright will subsist when the database constitutes, by virtue of the choice or arrangement of the material, an intellectual creation particular to its author. Here, the creator of a database will enjoy the same exclusive rights (reproduction, distribution, adaptation, etc.) as arise in respect of other copyright works. In 2012 the ECJ ruling in *Dataco v Yahoo* (case C-604/10<sup>46</sup>) provided further clarification in relation to the 'author's intellectual creation' requirement necessary for databases to attract copyright. The Court concluded that this requirement would be satisfied when, through the selection or arrangement of the data which it

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<sup>46</sup> ECJ C-604/10, <http://curia.europa.eu/juris/document/document.jsf?text=&docid=119904&pageIndex=0&doclang=EN&mode=lst&dir=&occ=first&part=1&cid=18964>.

contains, the author expresses creative ability by making free and creative choices, and thereby puts his ‘personal touch’ on the work. By contrast, it will be absent when construction of the database is dictated by technical considerations, rules or constraints which leave no room for creative freedom.

As noted, insofar as a database fails to satisfy the intellectual creation criterion needed for copyright protection, it may still qualify for protection under the secondary, *sui generis* right. The provisions in respect of the latter right are set out in Chapter III (articles 7-11) of the Database Directive. First, under Article 7 (1), the maker of the database is given the right in respect of “a database which shows that there has been qualitatively and/or quantitatively a substantial investment in either the obtaining, verification or presentation of the contents to prevent extraction and/or re-utilization of the whole or of a substantial part, evaluated qualitatively and/or quantitatively, of the contents of that database”. Here the reference is to the extraction (defined in Article 7 (2) (b) as “permanent or temporary transfer of all or a substantial part of the contents of a database to another medium”) of the whole or a substantial part. However, according to Article 7 (5), the repeated and systematic taking of insubstantial parts of the data may also infringe the *sui generis* right, insofar as this “unreasonably prejudice[s]” the database maker’s legitimate interests.

Under Article 7 (3) the database right can be transferred or assigned or granted under a contractual licence, and if the database is made available to the public, then according to article 8 (1) it will be permissible for the “lawful user” to do the acts otherwise prohibited under article 7 (1). However, this remains subject to an obligation on the lawful user under 7 (2) not to do acts that “conflict with normal exploitation of the database or unreasonably prejudice the legitimate interests of the maker of the database”. It is further provided, in Article 9 (b) that member states may provide in their domestic legislation for the right of lawful users, without the authorization of the database maker, to extract a substantial part of the database “for the purposes 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”. According to Article 10 of the Database Directive, the *sui generis* right to databases expires “fifteen years from the first of January of the year following the date of completion [of the making of the database]”. However substantial changes to it, “which would result in the database being considered to be a substantial new investment” will qualify the (updated and amended) database incorporating those changes for a further fifteen-year term of protection.

According to an express exclusion in Article 3(2) of the Database Directive, its protection will not extend to the contents of the database. It follows that data or information per se, besides not attracting

copyright (see part 5.2.2), will also not benefit from the sui generis right. Instead, the key legal regime for protecting information has a non-proprietary basis, in the form of rules relating to the misuse of confidential information, including trade secrets and ‘know how’. Admittedly, the rules in question differ in different jurisdictions, including between EU Member States; indeed some countries do not recognize such rules. However, in broad terms such an action – where it exists - permits a party to claim an injunction and/or damages where it can show one of two things: either (1) that it was an express or implied term of a contract between it and the other (disclosing) party that a given item of information would be treated as confidential (i.e. not be disclosed); or (2) (in the absence of any contract) that the nature of the information and/or relationship between the parties, means that it is equitable (fair and reasonable) in the circumstances for a court to impose on the latter such a confidentiality obligation.<sup>47</sup>

Recently, in November 2013, the EU Commission has issued a proposal for a Directive that would seek to harmonize the diverse, and often vague, national rules in this area, and provide a uniform redress mechanism for parties whose trade secrets are misappropriated by others. In doing so, it notes that, “in today’s knowledge economy, the capacity of companies to innovate and compete can be seriously harmed when confidential information is stolen or misused”.<sup>48</sup> The proposed Directive would introduce a common definition of trade secrets (in Article 2(1)), 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”.<sup>49</sup>

### 5.3.2 Potential relevance to the materials at issue in CHIC

As described in Chapter 4, three repositories are to be created in CHIC in WP 8, namely the model/tool repository, the (medical) data repository, and the in silico trial repository. In addition it is also planned in the same WP to make use of a distributed RDF repository solution to store metadata from each partner. The question concerning the sui generis right on different databases within the CHIC project will be, whether “there has been qualitatively and/or quantitatively a substantial investment in either the

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<sup>47</sup> See M. Spence, *Intellectual Property*, Oxford: Clarendon Press, 2007, pp 296 ff.

<sup>48</sup> See: [[http://europa.eu/rapid/press-release\\_IP-13-1176\\_en.htm](http://europa.eu/rapid/press-release_IP-13-1176_en.htm)].

<sup>49</sup> [<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2013:0813:FIN:EN:HTML>].

obtaining, verification or presentation of the contents”. One database covered by this sui generis right could be the medical data database, where verification and maintenance are crucial aspects for its providence and quality. This can be taken as a starting point for the discussion of any sui generis rights concerning the established databases within the CHIC project and the Foreground achieved. Nonetheless, from the factual point of view, it will need to be clarified how far the data provided and stored within the CHIC medical data database derives from previous clinical trials. In that respect it may be that these databases are just transferred in whole or essential parts from other databases and covered by a sui generis right already. No planned further verification of the contents is to be expected at this point, so the medical data database will not create any new sui generis rights within the CHIC project on that basis, though it may do so if the arrangement of the data is changed in a way that (while non-original in copyright terms) required significant investment of effort. This may include where as a result of effort new metadata files are incorporated in a manner linking them to original datasets (and providing an annotative scheme in respect of the latter). The only link to a verification and maintenance work provided by CHIC could be the Personal Identification Management System (PIMS), to guarantee the quality of the database in general. Similarly, when it comes to the model repository as part of the CHIC project, planned work will be done to annotate and describe the different models. This work may be seen as part of a validation and maintenance work and carried out within the CHIC project, also a matter requiring significant investment of labour, and consequently attracting the sui generis right.

When it comes to the model repository and the RDF repository as part of the CHIC project, planned work will be done to collect different models, annotate and describe the different models, and store them in different databases. This work can be seen as part of validation and maintenance work to be carried out within the CHIC project.

As regards the raw or ‘micro-’ data collected by the relevant partners and used to populate the repositories, this could be protected in some circumstances through confidentiality rules against disclosure and/or misappropriation. In this respect, the CHIC Consortium Agreement includes, in clause 10, specific contractual non-disclosure obligations to protect partners from having the information that they provide as background to the project (and mark as confidential) from being disclosed on by the partner(s) to whom they provide it without consent. Indeed, pursuant to 10.2, this obligation is extended to a period of five years after the termination of the project.

At the same time, 10.9 makes clear this does not “prevent the communication of any information: (a) To any Affiliate or to any other third party (including any other Party), insofar as strictly required for the

proper carrying out of the GA and/or this CA; or (b) To any third party (including the public), insofar as strictly required for (i) technical reasons and (ii) permitted Use of Foreground”. In fact it is apparent that rules whose effect was to “lock up” the data required (or indeed generated) as part of projects like CHIC would run counter to open data initiatives, which also form a core part of the EU’s overall research project funding strategy.<sup>50</sup>

## **5.4 Patent**

### **5.4.1 Overview**

Patent law is a form of intellectual property that protects the right of inventors to exploit technical inventions (products and/or processes) they have made. In this regard, it may be contrasted with copyright law, whose principal focus is the protection of creative, non-technical assets. Patent rights can be held by an individual or group, such as a company, and while they may be retained by the original inventor of the patented invention, such rights (as in the case of copyright) are often transferred – by way of assignment or licence - to another person or group for exploitation purposes. The patent in essence confers on the patent holder a monopoly exploitation right in the invention, enabling him (for the duration of the patent) to stop anyone else from using the invention without his permission. As in the case of copyright, there has been a substantial (though not complete) degree of international harmonization of the law through a number of important legal treaties, such as the 1883 Paris Convention, and the WIPO-administered Patent Cooperation Treaty (PCT) whose original version was signed in Washington in 1970.

A very important aspect of patent law is that (in contrast to copyright) patents must be applied for through a registration procedure, resulting - where successful - in the grant of the right by the relevant patent authority. This process largely occurs at national rather than international level, i.e. patents in respect of a given invention must be applied for and will be conferred on a territorial basis. However, in Europe there is also provision for Europe-wide patents to be granted by the European Patent Office in Munich (EPO), following a uniform registration procedure. There are currently thirty-eight member states that participate in the EPO system, including all EU member states, as well as Albania, Iceland,

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<sup>50</sup> See: [[http://europa.eu/rapid/press-release\\_IP-13-1257\\_en.htm](http://europa.eu/rapid/press-release_IP-13-1257_en.htm)].

Liechtenstein, Monaco, San Marino, Serbia, Switzerland, Turkey, and the (former Yugoslav) Republic of Macedonia.

The European framework for patentable inventions is set out in the European Patent Convention (EPC), which is administered by the EPO. According to Article 52 (1) EPC, “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”. These requirements are then elaborated on in Articles 54, 56 and 57 EPC, respectively. Essentially, that of ‘newness’ means the invention must go beyond the existing state of the art (i.e. not already be publicly available anywhere in the world); that in respect of an inventive step (often also referred to as the ‘non-obviousness’ test) concerns the question whether, though in some degree new, the invention is simply an incremental, more or less self-evident, development of what is already out there. This is judged according to whether the step in question would have been obvious to an average, skilled, but unimaginative, person working in the relevant field. Finally, the requirement of industrial application means that the invention should have utility, i.e. a tangible use in addressing a defined technical issue.

As well as these positive preconditions for patentability, there are also some matters that are expressly excluded a priori from patent protection. Several significant exclusions in this regard are contained in Article 52 (2) of the EPC in respect of “(a) discoveries, scientific theories and mathematical methods; ... (c) schemes, rules and methods for performing mental acts, playing games or doing business, and programs for computers; and (d) presentations of information”. Nevertheless this exemption shall apply, according to Article 52 (3) EPC, only to “such subject-matter or activities as such”. A further, pertinent exclusion from patentability, found in Article 53 (c) EPC, relates to, “methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body”; however this will not apply (i.e. prevent the patenting of) “products, in particular substances or compositions, for use in any of these methods”.

As already noted, patents must be applied for. Article 58 EPC specifies that the patent “may be filed by any natural or legal person, or any body equivalent to a legal person by virtue of the law governing it”, and according to Article 60 EPC it is prima facie the inventor who will own the right. The filing of a European patent follows a complex procedure that covers both legal and technical expertise, involving the need to assess the previous state of the art and other patentability conditions. If granted, then pursuant to Article 63 (1) EPC, “the term of the European patent shall be 20 years from the date of filing

of the application”. However, under Article 86 (1), a prerequisite for enjoying the full term is the payment of a yearly “renewal fee for the European patent application”. As a consequence “If a renewal fee is not paid in due time, the application shall be deemed to be withdrawn”.

## 5.4.2 Potential application of patent law in relation to CHIC

Prima facie the option of seeking patent protection for materials developed in CHIC (in addition to relying on any copyrights) might be considered. This is the case given that, as discussed earlier, though copyright protects the expression of ideas, in terms of the code written and used in the software components of the CHIC hypo- and hyper-models and their surrounding infrastructure, it does not protect the underlying idea of hyper-models and/or their use for diagnostic purposes. It follows that, while third parties would not be able (without authorisation) to copy and use the specific CHIC software, there would be nothing to prevent them developing their own competing hyper-models using alternative software. By contrast, patent protection, if granted, would prevent unauthorised competition of this nature.

Nonetheless, it must be acknowledged that there are several legal and practical hurdles in the way of obtaining patents for the CHIC models. The first of these concerns whether such software-based computer models are patentable as inventions at all, or rather fall within the excluded category of ‘computer programs as such’ under Article 52 (2) (c) and (3) of the EPC (referred to in part 5.4.1 above). The issue of software patentability in Europe is, as the EPO itself notes, currently “a hot topic” in the patent world, with a number of recent disputes concerning such applications reaching the EPO’s technical Boards of Appeal (TBA), as well as (in the case of national patent applications) courts in EPC member countries.<sup>51</sup> In this regard, a particular source of interpretational difficulty has been the meaning of the words “as such” in Article 52 (3) EPC, demarcating between non-patentable computer programs and those that are not “programs as such” (and hence remain patentable). The EPO’s own approach has been to draw a distinction between pure programs per se, which implement an algorithm in source or object code without producing an external technical effect, and what it terms “computer

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<sup>51</sup> See: [<http://www.epo.org/news-issues/issues/software.html>]. In 2002 the European Commission proposed a Directive that would have allowed for patenting of computer software by disapplying the exclusion under Article 52(2) EPC. However no consensus could be reached either on the desirability in principle or ambit of the proposal, and it was rejected by the European Parliament in 2005; see J. Jirsa, “Failure of the Directive on the Patentability of Computer-Implemented Inventions”, at: [[http://is.vsfs.cz/el/6410/leto2006/BK\\_PIPr/um/57894/AContribution-Final.pdf](http://is.vsfs.cz/el/6410/leto2006/BK_PIPr/um/57894/AContribution-Final.pdf)].

implemented inventions” (CI’s). The latter, while involving the use of a computer program as a means, “produce a ‘further technical effect’ [that goes] beyond the inherent technical interactions between hardware and software”<sup>52</sup>.

In this regard recent decisions of the TBA, such as *Microsoft (Clipboard format)* [2006] EPOR 39, and *Sharp/Graphical Interface* [2008] EPOR 32 stress the need for the subject of the patent to provide some added functionality (allowing the user to perform a task he was previously unable to); as opposed to simply presenting the user with cognitive aesthetic content. This may appear consistent also with a further express exclusion from patentability under Article 52 (2) (d) and (3), namely of “presentations of information [as such]”. However, in the light of the constantly developing case law, including decisions that are not always easy to reconcile with one another, this remains a complex and uncertain field. As one leading textbook in the area notes, “there is no bright line between what is, or what is not, within the exclusions [of software patentability] and the border has proved difficult to delineate”.<sup>53</sup> As the EPO itself notes, its granting practice is also significantly stricter than that of the US Patent and Trademark Office, “where patent protection for software is granted, even if it does not solve a technical problem”.

As regards the specific implications for CHIC, on our present understanding we believe the hypermodel concept would be close to the borderline in terms of whether it would qualify at the outset as a patentable invention under the EPC system. Thus it might be argued that the models, in simulating tumour growth, essentially present cognitive content (information) to the persons (doctors) deploying the models, rather than producing an autonomous technical effect. A further and independent problem that could arise in this regard also relates to the exclusion from patentability under Article 53 (c) EPC of “methods for treatment of the human...body by surgery or therapy and diagnostic methods”. The policy background to this exclusion, which applies to treatment ‘methods’ as opposed to medical devices or products, is to preserve the clinical decision-making freedom of doctors in the manner in which they approach the diagnosis of their patients and select therapies in response. Where a new method has the potential to bring powerful advantages for treatment and care (which the CHIC hypermodel approach if successful undoubtedly has), doctors ought not to be denied access or use due to there being a patent-based monopoly in the method.

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<sup>52</sup> See EPO, “Patents for Software?”, available at:

[http://documents.epo.org/projects/babylon/eponet.nsf/0/a0be115260b5ff71c125746d004c51a5/\\$FILE/patents\\_f or\\_software\\_en.pdf](http://documents.epo.org/projects/babylon/eponet.nsf/0/a0be115260b5ff71c125746d004c51a5/$FILE/patents_f or_software_en.pdf).

<sup>53</sup> D. Rowland et al, *Information Technology Law*, Routledge, 4th Ed., 2012, p. 377.

Assuming, however, that the CHIC models are classified as computer implemented inventions, and also seen as a ‘product’ rather than a ‘method’ for medical diagnosis and treatment, then the need remains for them to pass the further general patentability requirements, in particular by displaying novelty and inventive step. As the EPO states, it “does not grant patents for applications for inventions that make no inventive technical contribution by way of their technical features over the knowledge available at the point at which the application was first filed, regardless of what the application is for. This is the essence of inventive step or non-obviousness in patent law in Europe”.<sup>54</sup>

As noted in part 5.4.1, the requirement of novelty or newness involves showing that the technical inventive idea forming the subject of the patent is not part of the existing state of the art, by previously being published or made available in the world. In this regard, a significant prima facie difficulty for the hypermodel idea, and associated ideas of using networked computer model simulations in the field of medicine, are naturally widely known about, precisely through their dissemination in CHIC itself, as well as other similar projects running under the auspices of the VPH community and beyond. Similar problems may arise in relation to making out the necessary inventive step within the project. If this is put forward as the amalgamation of discrete hypomodels into larger hypermodels, then this might be seen as an incremental application to the field of medicine of techniques already deployed in other fields of activity (e.g. architectural modeling); if so it may then fail the inventiveness test under Article 56 EPC by being judged obvious to a person skilled in the art. At the same time this does not exclude the possibility that specific components developed by partners within CHIC could satisfy the relevant requirements on an individual basis.

To the extent that the substantive legal requirements for patentability are satisfied, there remains the need to register the invention in question for the patent right to actually exist. The process of filing patent applications, as described in part 5.4.1, is complex, and will usually require the services of specialist patent attorneys in order to draft and check the relevant claims. The associated costs of this process, as well as the registration (and renewal) fees payable to the applicable patent office, can also mount up, typically running into thousands of Euros.

For the various reasons adumbrated above, LUH is of the view at this stage of the project iteration that the patenting route is likely to be inappropriate for the materials developed in CHIC. This applies at least to the potential overall strategy the CHIC consortium develops in respect of jointly developed foreground, including the overall hypermodel concept. It remains though without prejudice to any

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<sup>54</sup> EPO, “Patents for Software?”, op cit.

decision a particular partner might take in relation to seeking patents for its own individual work. Naturally, any such partner would, as foreseen by the consortium agreement, still need to grant access to its invention (through an appropriate licence) so as to allow the successful exploitation of the project. (Licensing issues, which arise equally with the other forms of project IP, notably copyright, will be discussed in Chapter 7.)

## **5.5 Conclusions**

As has been discussed in this Chapter, the key IPR that is likely to be of broadest relevance within the CHIC project is copyright; by contrast, the sui generis database right while relevant, especially as a fall-back in cases where material due to lack of originality fails to qualify for copyright, is only applicable to the organisation and collection of materials into the CHIC repositories, as opposed to software code. For its part, while potentially applicable to software – insofar as this is deemed part of a computer implemented invention - the application of patent law remains uncertain and problematic: thus doubts may arise whether the CHIC hypermodels would satisfy the stringent patentability requirements under the EPC. Moreover it should be noted that the application preparation and registration processes (whether or not ultimately successful) also have significant cost implications. Though recourse to patenting should not be excluded a priori, this is a matter best left to the discretion of individual partners (subject to the terms of the CHIC grant and consortium agreements); in our view it is not an option the consortium as a whole should pursue at this stage.

The focus of the present chapter, as was noted in the introduction, has been to delineate and describe the key potential IP rights applicable to works and other material falling within the CHIC project. However, an extremely important further question (assuming a relevant right is found to subsist) is the matter of ownership: which parties – inside the CHIC consortium (in the case of foreground), or potentially outside it (in the case of some project background) own the given rights? And if there is more than one right-holder in a particular work what are their entitlements and obligations inter se? Resolving these issues is imperative both for determining the identity of the party or parties entitled to exploit a given right, and the manner in which they may do so. This topic is addressed in the Chapter 6.

## 6 IPR ownership issues in CHIC

### 6.1 Introduction

This chapter builds upon the analysis in the previous chapter by considering a further critical facet of IPR, namely the question - once it has been established that relevant IPR subsists in given material (a work, invention, etc) - of its attribution; in other words, which person or entity (legal and/or natural) will be invested with the IPR in question? As noted in Chapter 6, it is the owner to whom the law reserves in the first instance the exclusive right to deal relevant material in key ways central to its economic exploitation (e.g. the right under copyright to copy, distribute, and adapt the work). It follows that determining his or its identity will be an essential precursor for the material's exploitation, and for the avoidance of potentially infringing acts (through using it without gaining the necessary authorisation of the owner).

In the present Chapter, and in the light of the conclusions in the last Chapter that patent law protection is not currently an appropriate avenue for the CHIC project to follow, the focus will be principally on the law of copyright (with some discussion also of the database right). The key principles discussed, though, also apply in a broadly similar way to other IPR regimes such as patent. In this regard a particular focus will be upon the complex issues of (multiple) ownership in relation to derivative and/or composite works. As will become apparent, this is also of key relevance in CHIC both as regards background material brought to the project by the various partners, and the collaborative creation of project foreground. An understanding of these issues provides an essential starting point for the subsequent discussion in Chapter 7 of how the CHIC partners, individually and collectively, may choose to exploit their IP rights during and at the conclusion of the project, including the selection of suitable licences.

### 6.2 Copyright authorship/ownership issues and their application to software

As noted in Chapter 5, the copyright in a work usually belongs in the first place to the person who created it, i.e. its author. However, this rule is subject to exceptions. The main one concerns the position of employees who produce copyrightable works in the course of their employment, an issue where there is also a divergence between common law and civil law approaches. Thus, under the common law tradition, in such a case it is the employer rather than the employee who is the first owner of the copyright, unless there has been an agreement to the contrary.<sup>55</sup> By contrast, in civil law jurisdictions (which usually confer authorship on natural persons only, not firms or other organizations), the rule is

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<sup>55</sup> See J. Davis, *Intellectual Property Law*, London: Butterworths, 2001.

that the employee author is the first owner, albeit it is common for employment contracts to provide for an automatic transfer of the exploitable aspects of the copyright to the employer, meaning that the latter (also where a legal not natural person) acquires the relevant rights by contract.<sup>56</sup> In respect of the moral rights in the work, such as the right of an author to be identified as the author of their work, these generally are inalienable meaning they cannot be assigned; they can however be waived, and usually the employment contract will also provide for this to occur as necessary for the work's exploitation.

A further issue that may arise concerns the copyright ownership of works produced under commission. Here if the commissioning party itself takes an active role in the process amounting to the contribution of original expressive material that is further worked up by the commissioned party, then the product could amount to a joint work in which each has a share of the copyright (see below). If however, the input of the commissioning party is limited to general ideas and suggestions, then the default position (in line with the ideas-expression dichotomy: see Chapter 5) is that the commissioned party alone, which has translated the ideas into concrete expression, will enjoy copyright. This may, however, be subject to terms within the contract of work, by which the commissioned party agrees to transfer the copyright to the commissioning party on completion of the work. In some cases, where it deems this reasonably necessary in order to make commercial sense of the contract between the parties, a court may also imply an assignment, or more commonly the grant of a non-exclusive licence from the commissioned party to the commissioning party, in order to allow the latter to make use of the work.<sup>57</sup>

As regards copyright in software, the ownership position in relation to employee creations has been put on common footing in the European Union, by virtue of the Software Directive 2009/24/EC.<sup>58</sup> This provides in Article 2(1) that, "the author of a computer program shall be the natural person or group of natural persons who has created the program or, where the legislation of the Member State permits, the legal person designated as the rightholder by that legislation"; it goes on to stipulate under Article 2(3): "Where a computer program is created by an employee in the execution of his duties or following the instructions given by his employer, the employer exclusively shall be entitled to exercise all economic rights in the program so created, unless otherwise provided by contract".

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<sup>56</sup> See the Unesco ABC Guide to Copyright, at:

[http://www.unesco.org/fileadmin/MULTIMEDIA/HQ/CLT/diversity/pdf/WAPO/ABC\\_Copyright\\_en.pdf](http://www.unesco.org/fileadmin/MULTIMEDIA/HQ/CLT/diversity/pdf/WAPO/ABC_Copyright_en.pdf).

<sup>57</sup> See e.g. the decision of the English High Court in *Richardson (John) Computers Ltd v Flanders* [1993] FSR 497.

<sup>58</sup> Available at: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:111:0016:0022:EN:PDF>.

So far we have considered ownership rules as they apply to single-author works. However, it is standard practice in many instances, including in industries such as that for computer software, for two or more persons to collaborate together in order to produce a given work. Assuming that each author contributed expression (rather than mere ideas) and that this was sufficiently original to attract copyright,<sup>59</sup> this leads to the question of how copyright should be divided between the authors. Here, while the detailed legal rules vary across different jurisdictions (including between EU member states), copyright law recognizes a broad distinction between so-called “joint works” (where the contributions of each author to the whole work cannot be clearly separated out), as opposed to “composite works”, where the respective contributions can be distinguished.<sup>60</sup> In the case of joint works, the individual contributors will be co-authors who jointly own the rights in the work. Unless otherwise contractually agreed, they must generally exercise their copyright together, and share profits from the exploitation of the work equally. While in principle each author retains the right to veto a given exploitation (by refusing consent), this right may not be exercised unreasonably. In respect of computer software, the Software Directive recognizes the possibility of such joint creations in Article 2(2), stating: “In respect of a computer program created by a group of natural persons jointly, the exclusive rights shall be owned jointly”.

As noted, a second possibility in relation to multi-authored works is that a composite work (sometimes also termed a collective work) will result, consisting of separable contributions by each author. This would be the case, for example when two authors combine their efforts to write a book together, but agree to contribute distinct chapters. In such a case, each author would own distinct copyright in their own part of the book. However, in addition there may be copyright in the overall work (so far as original effort was expended on arranging and compiling the different parts): this would be held by the editor/compiler. Another possibility would be the integration of works in different media to form a unified whole, such as where lyrics are added to music to create a song. Here the composer and the lyricist would enjoy separate copyright in their contributions (i.e. the music and the lyrics, respectively). However, there would also be copyright in the song, as the composite product, which – if the two of them collaborated in the integration – the composer and lyricist would enjoy jointly; if just one of them (or indeed a separate party) undertook the integration, then the latter would have the copyright.<sup>61</sup>

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<sup>59</sup> See the Unesco Copyright Guide, op cit.

<sup>60</sup> Ibid.

<sup>61</sup> J. Davis, *Intellectual Property Law*, op cit.

In some cases collective/composite works may also qualify as “derivative works”, where the latter term is understood broadly to include multi-authored works in which, rather than the composite being created at one and the same time (synchronously), a pre-existing work is later added to by or integrated with a second work to form a new work. However, on other occasions a derivative work will remain a single work, as with adaptations, where a pre-existing work is transformed into a new medium or expressive form, e.g. a book is translated into another language. For each of these cases similar rules will generally apply - with some national variations of detail<sup>62</sup> - as do with respect to synchronous composites: thus provided the derivative is a new original work, it will attract copyright in its own right, held by the party who created it. This will be, at the same time, without prejudice to the separate (older) copyright in the pre-existing work(s) on which the derivative is based. The original copyrights will be retained by the original author(s); in order to use the derivative work, a third party will accordingly need the permission of both/all right owners.

Computer software, as has been stated, is an artefact that is frequently produced by the collaborative endeavours of several authors, a process that may occur in the various combinations discussed above. As already mentioned, if two programmers together produce a single indivisible program, then Article 2(2) of the Software Directive confirms that joint copyright ownership will arise. However, also very common, given the inherently modular structure of much software, is the creation of composite works, where separate coders write self-standing modules that are linked together. Here (always subject to the need for sufficient originality in preparing and/or writing the code) there is a complex set of possibilities. Thus each module-coder will enjoy copyright in their component as an original literary work. In addition, in line with the general ownership rules discussed above, a developer who expends effort in compiling/integrating the different components will enjoy copyright in the overall compilation; moreover, where the integration involves creating further code to achieve interoperability between modules, separate copyright will subsist in this code as well.

Though the above processes may be synchronous, it is more common for them to occur sequentially over time, so that software components originally produced at t1 are subsequently picked up and used by another developer at t2 to form a derivative work. Indeed this way of working is seen by many as a

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<sup>62</sup> See the comparative factsheet on IPR joint ownership, published by the EU Commission, available at [http://www.kowi.de/Portaldata/2/Resources/FP6/ipr\\_joint\\_ownership.pdf](http://www.kowi.de/Portaldata/2/Resources/FP6/ipr_joint_ownership.pdf).

desirable norm that informs the “open source”<sup>63</sup> licensing approach to software. These issues, including the diverse senses in which derivative works may be understood and defined (for the purposes of different licenses) are covered in detail in Chapter 7. However, an important aspect that may be noted already is that, besides integrating modules to form a larger composite program, a later developer may also change and adapt the original code within a given software module, e.g. to tailor it to perform a new function. In this case (again, assuming the changes involve sufficient expressive originality) the result will be a derivative work in the form of an adaptation of the original module. In terms of copyright ownership, it will not in fact make much difference whether what the later developer does is integrate unaltered individual modules into a composite or (also) adapt them in the process: in both cases the original module-coder retains copyright in their module, with the later developer obtaining copyright in the derivative (be it a composite and/or an adaptation). However, as noted in Chapter 7, it may – depending on the terms on which use of the module was licensed - have implications for exploitation-options available to the developer in respect of the derivative work.

### **6.3 Ownership implications for CHIC**

In relation to the materials to be used in CHIC, it is clear copyright ownership issues will be relevant both as concerns the project background and in relation to the project foreground. First as regards the background, this comprises pre-existing knowledge (materials, information, and rights in the same) that each partner has developed/acquired from work prior to the project, and which is needed by it or another partner to implement or use foreground in the project.<sup>64</sup> Under FP7 rules, background may take the form of information, inventions, databases, tangible assets (e.g. a sample), as well as IPR, either owned (jointly or not) or held under a contract, such as a license agreement.<sup>65</sup>

In terms of the existing models and other software components that CHIC partners will bring as background to CHIC, it is apparent that some, namely those incorporating software modules created by third parties, will qualify as derivative works. In many cases the relevant third party will have authorised the use of the code by others under an open source licence. However, this does not affect the underlying IP rights position, which is, as discussed in part 6.2, that the third party retains the copyright in its original software code; for its part the subsequent user/developer (here the CHIC partner) will acquire

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<sup>63</sup> See D. Rowland et al, *Information Technology Law*, op cit, p. 413.

<sup>64</sup> See the European IPR helpdesk fact sheet, Background in FP7 Projects, available at [<http://www.iprhelpdesk.eu/sites/default/files/newsdocuments/background%20in%20FP7.pdf>].

<sup>65</sup> Ibid; (for a definition of Fore- and Background as used within FP7-projects see page 7).

separate copyright in the derivative it created. This may have significant implications for the way that the model can be used and further developed for the purposes of CHIC. On the one hand, it may be assumed that the model can be used – indeed if it could not be, the relevant partner would not under FP7 rules (as well as by virtue of the exclusions in attachment 2 of the CHIC Grant Agreement) be required to make it available as background in the first place. On the other hand, as further discussed in Chapter 7, open source licence models may – where of a restrictive (or ‘controlled’), ‘copyleft’ form – impinge on the future use by the consortium of foreground generated using the derivative.

The second implication for the CHIC project relates to the so called Foreground that stands for the “tangible and intangible results, including for example information and knowledge, whether or not it can be protected, which is generated under the project”.<sup>66</sup> First of all the models created and coded needs to be investigated for their IP provenance including potential ownership rights. In addition various databases will be established, e.g. a model repository comprising annotations and descriptions. As discussed in Chapter 5 all these aspects of the CHIC project might be subject to subsisting IPR. In this regard the author of the model implemented in a computer program is the person who solely or jointly coded the software or the relevant employer. As the precondition of coded software does not differ according to whether the work is a model or a hypermodel, but is based on the expressed code, this per se does not affect the relevant analysis. However, by its nature a hypermodel will incorporate an additional level of complexity as an amalgamation (composite) of models that themselves may often be composite and/or derivative works. When the need for an extra interoperability layer of code is factored in as well, together with linking between the models and repositories, the potential for multiple copyright and other IPR multiplies.

Here, a question remaining to be answered is which partner will qualify as the author and/or owner. This is important to know as it will determine who has the primary obligation to protect and exploit the valuable CHIC foreground in accordance with FP7 rules, as set out in the Grant Agreement (obligations to be examined in Deliverables D4.3.1 and D4.3.2). Prima facie each contributing partner (as employer of the team of coders) would be regarded as the owner of the copyright in the part it contributed, where separable; nonetheless, any conflicting rules in particular national jurisdictions in respect of certain categories of employees will need to be checked for their potential impact on any partner. Insofar as the

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<sup>66</sup> IPR Helpdesk, Introduction to IP Rules in FP7 Projects, available at: [<http://www.iprhelpdesk.eu/sites/default/files/relateddocuments/Factsheet%20IP%20rules%20FP7%20June%202011.pdf>].

distinct contribution of each partner cannot be separated out, but assuming each made a sufficiently original contribution, then a joint ownership of all will arise. The CHIC Consortium Agreement covers these aspects, allowing for a separate ownership in principle. According to 8.1 CA, the partner who carried about the work is to be regarded as owner alone. The question, when the exemption applies under 8.1, where a Foreground forms part of the work of different partners such that “it is an indivisible part” will require empirical investigation of concrete modelling practices as the project develops. Further guidance addressing this matter will be provided in Deliverable D4.3.1, to be submitted in M14.

The approach in the CHIC CA is mirrored in the general FP7 rules, as detailed in the Grant Agreement. As Annex II of the latter states at II.26: “1. *Foreground* shall be the property of the *beneficiary* carrying out the work generating that *foreground*; 2. *Where several beneficiaries have jointly carried out work generating foreground and where their respective share of the work cannot be ascertained, they shall have joint ownership of such foreground*”.<sup>67</sup> In the latter case the partners should establish an agreement governing the allocation and exercise of their joint ownership. However, in default of such an agreement each partner may – subject to notice and provision of fair compensation - grant non-exclusive licences to exploit the foreground to third parties. A likely approach for the amalgamation of different coded models will involve the use of modular software components, which may allow the work of different partners to be differentiated. In that respect a joint ownership would be excluded. In the very end, the question of joint ownership will be decided in the course of the project and subject to ongoing concretisation of the work planned and carried out.

Similar ownership questions arise in respect of the CHIC medical data repository in terms of identifying the holder of copyright (insofar as it subsists) and/or the alternative database right. As regards the general approach to such rights in databases, the Database Directive 96/9/EC<sup>68</sup> legislates rules that mirror those in respect of copyright in software. Thus Article 4 (1) of the Directive provides that “The author of a database shall be the natural person or group of natural persons who created the base or, where the legislation of the Member States so permits, the legal person designated as the rightholder by that legislation”, while 4 (3) specifies that, “in respect of a database created by a group of natural persons jointly, the exclusive rights shall be owned jointly”. It appears that this approach is intended to apply *pari passu* also to the secondary sui generis right acquired by the “maker” of the database under Article 7.

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<sup>67</sup> See: FP7 Grant Agreement - Annex II General Conditions, available at: [ftp://ftp.cordis.europa.eu/pub/fp7/docs/fp7-ga-annex2-v3\\_en.pdf](ftp://ftp.cordis.europa.eu/pub/fp7/docs/fp7-ga-annex2-v3_en.pdf).

<sup>68</sup> <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31996L0009:EN:HTML>.

In terms of the latter right, one could argue that in CHIC much of the requisite “substantial investment” in obtaining and verifying the database contents occurred during medical trials already. In consequence one set of holders of the database right would be the clinical partners themselves, who contributed the data as Background to the project. Equally, if during the project technical partners invest significant effort in the presentation of the contents, they may also acquire rights. Up until now, there has been no suggestion that in addition the medical databases derive from any third party contributions either in whole or in part. Concerning the model repository it is to be assumed, as far as the models are acquired from different sources, such as periodicals or journals, that there will be no reuse of an existing database as such. As to the question, who owns the sui generis right, at this stage a joint ownership appears quite likely because the database arguably forms a coherent work by definition. On this basis, the work of the database may be seen as indivisible and all partners working on the model repository would enjoy joint ownership.

## **6.4 Conclusions**

As has been discussed in this Chapter, establishing ownership of the copyright (and, where applicable the database right) in respect of the software and other materials in CHIC requires addressing complex issues of multiple ownership of derivative and/or composite works. This will indeed arguably be an inherent aspect of virtually any sophisticated collaborative enterprise such as occurs in a multi-partner project. In this regard the key contractual project documents, notably the Grant Agreement and the CHIC Consortium Agreement already provide some rules for joint ownership. At the same time, the nature of software development involving the ongoing reuse, adaptation, and combination of existing code creates a complex situation, in which a sound appreciation of the underlying IP law rules is necessary to avoid pitfalls and ensure successful exploitation of the materials developed in the project. As stated earlier, the next chapter, Chapter 7, takes this discussion further by considering licensing options available to the relevant IP-owners in the project, especially in respect of copyrightable software in the CHIC models and hypermodels.

## 7 Software licensing: implications for derivative works in CHIC

### 7.1 Overview

Existing software materials in many situations provide the foundation for creating new ones. As indicated in the previous chapters, CHIC will be utilizing existing models (some already coded into software) and other tools such as linkers for amalgamation of the models. In this regard, it is important to carefully consider the licensing conditions for making such derivatives. As noted in Chapter 6, the terms of the license adopted by a given (third party) coder of a specific module could restrict the ability of the developers of a derived work incorporating the module to choose the license under which to distribute their derivative. For example, if the original software license (inbound license) for a module from which a derivative work is obtained is permissive in nature, such as MIT or BSD-type license, the derived work can be distributed virtually under any license, so long as the proper notifications and disclaimers are included. By contrast, GPL-type licenses are infectious, giving little or no choice: for every GPL derived work must be distributed under similar GPL-type licenses (copyleft), unless separate permission is obtained from the original licensor to switch the license.<sup>69</sup> Apart from open source software, restrictions or other incompatibilities may also arise with commercial or proprietary licenses (such as where the license forbids making derivatives). Given these potential conflicts, it is imperative to have a clear approach to software licensing management at the earliest stage of any collaborative project. Whether based on free/open source software (FOSS) or proprietary ones, or both, a project may face some difficulties at the end if the component licenses are not compatible.<sup>70</sup> Below, we will look at the general legal understanding of software licensing and how CHIC can deal with issues of compatibility.

### 7.2 General framework of software licensing

Authors of software enjoy a level of control over the exploitation of their creation by imposing specific usage rules on the software. Licensing is a common way of exercising this control, being generally considered as a contract or declaration of permission granted by the licensor (the author of the software) to the licensee (the user of the software) to use software according to the license terms.<sup>71</sup>

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<sup>69</sup> Andrew Laurent, *Understanding open source and free software licensing*, 2004, O'Reilly, p.175

<sup>70</sup> Comparative factsheet on IPR management in software development, published by the EU Commission, pp. 11-13, available at: [http://www.iprhelpdesk.eu/sites/default/files/newsdocuments/Intellectual%20Property%20Rights%20Management%20in%20Software%20Developments\\_updated.pdf](http://www.iprhelpdesk.eu/sites/default/files/newsdocuments/Intellectual%20Property%20Rights%20Management%20in%20Software%20Developments_updated.pdf)

<sup>71</sup> Eben Moglen, "Enforcing the GNU GPL", 2001, available at: <http://www.gnu.org/philosophy/enforcing-gpl.html>. Other forms include: assignment, testamentary disposition.

Generally, depending on the nature of restriction imposed by the licensor, two broad approaches may be distinguished in relation to software licensing: proprietary licenses, and non-proprietary licenses – the latter encompassing free and open source licenses.

### 7.2.1 Proprietary licenses

Proprietary licenses encompass different types of licenses which impose certain conditions on how licensees can use the software, its source code, requirement for a financial contribution, or any other condition. Key points in proprietary licenses are the prohibition of software modifications, a strict control over software usage, no access to the source code, and financial obligations.<sup>72</sup> Examples of such licenses include freeware and shareware.<sup>73</sup> Roughly, proprietary software licenses could be classified in terms of usage into:

- i. End user licensing: licensing to a specific individual;
- ii. Node licensing – licensing to a specific hardware;
- iii. Site licensing – licensing to a dedicated geographical space or company;
- iv. Network/Floating licensing – dedicated to use in a given network.<sup>74</sup>

Apart from the above categorization, cloud computing has made it possible for software to be offered as a service on a large scale. Software as a Service (SaaS) is often referred to as software-on-demand - akin to renting software rather than buying it, where users are able to access software applications over the Internet.<sup>75</sup> Consumers do not need to install the software on site. Unlike on-premise software which are usually licensed in perpetuity, with a single up-front cost for each user or site, or (in the case of custom-built applications) owned outright, SaaS applications are often licensed with a usage-based transaction model, in which the customer is only billed for the number of services used.<sup>76</sup> The service level agreement (SLA) for a SaaS offering may impose certain conditions and restriction on usage.<sup>77</sup>

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<sup>72</sup> IPR Helpdesk on IPR\_Management\_in\_Software\_Developments, op cit, p. 8

<sup>73</sup> GNU, Categories of free and nonfree software, available at:  
<https://www.gnu.org/philosophy/categories.html#PublicDomainSoftware>

<sup>74</sup> IPR Helpdesk on IPR\_Management\_in\_Software\_Developments, op cit, pp.8-10.

<sup>75</sup> Christopher Millard (ed) *Cloud Computing Law*, Oxford university press, 2013.

<sup>76</sup> Gianpaolo Carraro and Fred Chong, 'Software as a Service (SaaS): An Enterprise Perspective', 2006, available at <http://msdn.microsoft.com/en-us/library/aa905332.aspx>

<sup>77</sup> See <http://www.gnu.org/licenses/agpl-3.0.html> for open source license for SaaS

## 7.2.2 Free and open source licenses

Traditional models of software licensing were mainly proprietary, imposing several restrictions on the licensee. In most cases, making derivative works was prohibited and the source codes were kept secret. These were hindering research and development; necessitating a new movement of “openness” in software licensing that tends to relax most of the proprietary restrictions. The free/open source movement (FOSS) developed out of the community mindedness of researchers to challenge proprietary ideology. It has to be stressed however, that “open source” does not necessarily mean no monetary compensation or no restriction in the scope of use. Payment requirements as well as usage restrictions can be enshrined in open source licenses, and violation of such obligations could result in a legal dispute.<sup>78</sup> However, unlike proprietary licenses, FOSS licenses do not prohibit modifying the software or making derivative works. Source codes are also openly published for anyone to use.

## 7.2.3 Public domain software

Non-proprietary software can further be divided into (free) public domain, and software that are protected even though they are open and permit modification such as FOSS. Public domain software refers to software that is not copyrighted. No restrictions are attached to using the software: they could be copied, modified, distributed without any encumbrance.<sup>79</sup> Some software in this category could be found in GitHub or Bitbucket. A movement for “copyfree”<sup>80</sup> license (or more accurately, a waiver) is similar to the public domain category, where software authors are encouraged to release their works without imposing any restriction on the end-user. Unlike the FOSS community where certain restrictions exist (such as the copyleft or prohibition on commercial use), “copyfree” is meant to give absolute freedom to users – they can redistribute derivative works under any license of their choice including commercial licenses.

## 7.3 Free/open source philosophy and its application to derivative works

Free software and open source software, although sharing similar objectives, refer to two different concepts, as can be seen from their philosophy and criteria for eligibility.<sup>81</sup> While free software is an

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<sup>78</sup> See, Raymond Nimmer, “Legal Issues in Open Source and Free software Distribution”, <http://euro.ecom.cmu.edu/program/law/08-732/Transactions/LegalIssuesNimmer.pdf>.

<sup>79</sup> <http://unlicense.org/>.

<sup>80</sup> <http://copyfree.org/>.

<sup>81</sup> For the purposes of this deliverable, both terms will be used as FOSS and will refer to one concept.

initiative of the Free Software Foundation (FSF),<sup>82</sup> open source software stems from the Open Source Initiative (OSI).<sup>83</sup> Essential criteria for any software to qualify as FOSS include the four freedoms as indicated by the OSI:

1. Freedom to use or run it for any purpose and any number of users;
2. Freedom to obtain the source code (in order to study how the software works);
3. Freedom to share, to redistribute copies of the software;
4. Freedom to modify, adapt, improve the software according to specific needs and to share these modifications.<sup>84</sup>

FOSS licenses could be broadly grouped into two families: permissive and copyleft licenses. **Permissive licenses** are generally compatible and interoperable with most other licenses; this includes tolerating merger, combination or improvement the covered source code, as well as redistributing the derived work under any license (including proprietary in some cases).<sup>85</sup> Examples of licenses in this group include BSD, MIT, Apache, etc.

**Copyleft licenses** on the other hand, have a viral or knock-on effect, imposing the use of the same license upon the user insofar as the distributed work (created by the latter) is a derivative of an original work covered by such license.<sup>86</sup> Examples include strong copyleft licenses such as the GNU GPLv2, GPLv3, and the EUPL. There is however a middle position (weak copyleft) found in some licenses such as the LGPL or the MPL, which try to compromise between the permissive licenses and strong copyleft requirements to the extent that covered components (and their specific derivatives) will always keep their primary license, but the combined application “as a whole” (even if it may be considered globally as a derivative) or its executable binary (a single program from the user point of view) can be distributed under any license.<sup>87</sup> This means, as mentioned in Chapter 6 and further described below in part 7.4.1, that a user who adapts/alters the code of the original software component when creating his derivative

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<sup>82</sup> <http://www.fsf.org/>.

<sup>83</sup> <http://opensource.org/>.

<sup>84</sup> However, the OSI has ten criteria. Apart from the four freedoms above, there are other conditions which differ between free and open source software. See: [https://joinup.ec.europa.eu/software/page/licence\\_compatibility\\_and\\_interoperability](https://joinup.ec.europa.eu/software/page/licence_compatibility_and_interoperability).

<sup>85</sup> [https://joinup.ec.europa.eu/software/page/licence\\_compatibility\\_and\\_interoperability](https://joinup.ec.europa.eu/software/page/licence_compatibility_and_interoperability).

<sup>86</sup> Jaeger/Metzger, Open Source Software, 2009, p 4.

<sup>87</sup> [https://joinup.ec.europa.eu/software/page/licence\\_compatibility\\_and\\_interoperability](https://joinup.ec.europa.eu/software/page/licence_compatibility_and_interoperability).

is required to license the latter on the same (weak copyleft) terms; however, this is not so if he simply integrates the (unaltered) component into a larger (composite) derivative work.

Permissive Licenses	Copyleft Licenses	
	Weak copyleft	Strong Copyleft
BSD	LGPL	GPLv2
MIT	MPL	GPLv3
Apache	EPL	EUPL
CDDL		Affero GPL

Table 1: Examples of commonly used FOSS<sup>88</sup>

**GNU General Public License (GPL):** is an open source, copyleft (share-alike) license and has version 3.0 (established in 2007) as its current version.<sup>89</sup> It contains a strong viral clause indicating that software derived from a GPL code must be redistributed under GPL license as well.

**Library GNU Public License (LGPL):** is a weaker version (version 3 currently) of the GPL designed to address the problems of program libraries where it would be possible to combine or use LGPL libraries with another libraries, without infecting the whole software. It allows the developer to convey a combined work under terms of his or her choice when certain conditions are fulfilled such as attributing the LGPL to the part of the component containing such library.<sup>90</sup>

**Affero GPL:** This is a modified version of the ordinary GNU GPL version 3 that is geared to SaaS. It has one added requirement: if a user runs the program on a server and lets other users communicate with it there, the server must also allow such users to download the source code corresponding to the relevant program. If what is running is a modified version of the program, the server's users must be allowed to access the source code in the modified form.<sup>91</sup>

<sup>88</sup> A fuller list could be obtained at [www.spdx.org/licenses/](http://www.spdx.org/licenses/).

<sup>89</sup> <http://www.gnu.org/licenses/quick-guide-gplv3.html>.

<sup>90</sup> See clause 5 of LGPL, <http://www.gnu.org/licenses/lgpl.html>.

<sup>91</sup> <http://www.gnu.org/licenses/why-affero-gpl.html>.

**Common Development and Distribution License (CDDL):** is a world wide, royalty free, non exclusive license, which allows developers to use, modify and share software (and the option to charge for it).<sup>92</sup> Modifications must be made available under the same conditions, but CDDL allows the addition of new terms to the license. CDDL also addresses potential patent rights in software, by providing a ‘patent license’. This allows developers to use code for which a patent has been granted without worrying about legal action being taken against them.

**Mozilla Public License (MPL):** The current version is 2.0. It allows modification and distribution of derived work in a larger work under the a new license as far the conditions of MPL are fulfilled.

**Berkeley Software Distribution license (BSD):** The original BSD license allowed developers to modify the original code and to distribute it. Developers are asked to attribute any work based on the original work to be attributed to the original source in any advertising material. The modified BSD license (1999) and the simplified BSD remove the ‘advertising clause’ and allow distribution and modification of code, as long as the specified copyright notice is made (Copyright (c) <year>, <copyright holder> All rights reserved). The modified BSD specifically prohibits developers from using the brand name or logo of the original source to advertise products derived from the original source.

**Apache:** The current version is 2.0 (established in 2004).<sup>93</sup> This license grants permission to distribute and change software, and includes a patent license. Developers must leave copyright and other notices, such as brand name etc, in the original source. Modified files must carry appropriate notices of the change in the file made by the developer.

**European Union Public Licence (EURL):** This is a free software license<sup>94</sup> that has been created on the initiative of the European Commission.<sup>95</sup> It has a copyleft comparable to the GPL's, and incompatible with it. Its current version is 1.1, but consultation on the draft of version 1.2 has been closed and the version is expected at any time. The EURL gives recipients ways to alternative license, and permits relicensing the work under the terms of other selected licenses such as the Eclipse Public License and the Common Public License. The EURL allows relicensing to GPLv2, because that is listed as one of the alternative licenses that users may convert to. It also, indirectly, allows relicensing to GPL version 3,

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<sup>92</sup> <http://opensource.org/licenses/CDDL-1.0>.

<sup>93</sup> <http://www.apache.org/licenses/LICENSE-2.0.html>.

<sup>94</sup> <http://directory.fsf.org/wiki/License:EURLv1.1>.

<sup>95</sup> <https://joinup.ec.europa.eu/software/page/eupl>.

because there is a way to relicense to the CeCILL v2, and the CeCILL v2 gives a way to relicense to any version of the GNU GPL.<sup>96</sup>

## 7.4 Software interoperability management

Apart from deciding which licensing model to adopt when developing new software, a component-based infrastructure (such as that in CHIC) will also need to overcome challenges in terms of the compatibility of individual licenses of the integrated components. As noted earlier, this is important because distribution of a derivative work may be restricted to the conditions of the original (inbound) license(s) from which it is derived. Incompatibility in this case occurs where a derived work is a composite of two or more source codes, in which the license conditions mandate incompatible actions or obligations. For example, under GPLv2, there is a viral clause that any derivative work must be distributed under GPLv2 license. A similar viral clause is also found in GPLv3 and EUPL, which brings a conflict in terms of finding a compatible license for distributing a derived work that makes combined use of these source codes. As this makes clear, licensing obligations, unless managed so as to avoid conflicts between incompatible terms, may impact adversely on the exploitation of derivative works.<sup>97</sup>

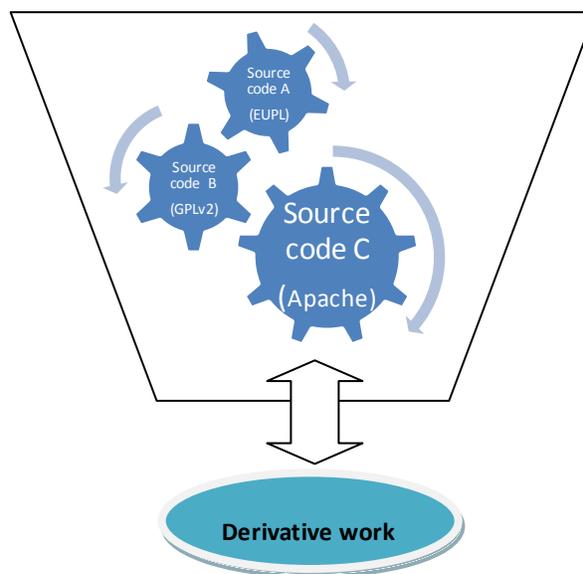


Figure 3: Possible ways of combining existing source codes and obtaining a derivative work

<sup>96</sup> <http://www.gnu.org/licenses/license-list.html>.

<sup>97</sup> Ibid.

Development of open source solutions may be complex, as software development itself generally occurs – as described in Chapter 6 – through (later) programmers adapting and integrating multiple existing components.<sup>98</sup> While the resulting application (or “solution”) may look like a single program from the user’s point of view, in fact, it may be a combination of many works (with different components covered by the different licenses favoured by each respective rightholder). In figure 3 above, it is assumed that the derived component is made up of three different source codes: component A licensed under EUPL, component B licensed under GPLv2, and component C licensed under Apache. The question is now under which license should the derivative be distributed? While Apache is generally compatible with most other licenses, there may be a problem in licensing the derivative because EUPL and GPLv2 are not compatible; each contains a strong copyleft clause. There are controversial solutions in the literature as to how open source license incompatibility may be solved. However, one major factor to consider is how software derivatives are created both under copyright law and the FOSS definitions.

Knowing whether a new software is a derivative determines how much a licensee (of the original software) has to give up when distributing the derived work (either alone or in combination with improvements made with other programs). As discussed in Chapter 6, generally, copyright law sees derivative work as “a work based upon one or more preexisting works, such as a translation, [...], reproduction, abridgment, condensation or any other form in which a work may be recast, transformed, or adapted.”<sup>99</sup> However, in computer programming, it may sometimes be difficult to determine when a derived work has been created from the original due to the complex nature of programs and how they interact with each other within a system. The issue is still controversial in the FOSS community as well as in the legal domain.

GPL licenses for instance, do not conceive derivative work entirely in the same manner as traditional copyright law, preferring to apply independent criteria for determining what qualifies as a derivative, including factors such as modification, dependency, interaction, time of linking, distribution medium, and location.<sup>100</sup> Thus in deciding when a derived work is made, technical factors such as linkage,

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<sup>98</sup> [https://joinup.ec.europa.eu/software/page/licence\\_compatibility\\_and\\_interoperability](https://joinup.ec.europa.eu/software/page/licence_compatibility_and_interoperability).

<sup>99</sup> US Copyright Act of 1976, 17 U.S.C., § 101.

<sup>100</sup> Luis Enríquez, “Dynamic linked libraries paradigms of GPL2 and GPL3 in contemporary software”, 2013, pp. 20-62, available at: <http://www.lulu.com/shop/luis-enr%C3%ADquez-a/dynamic-linked-libraries-paradigms-of-the-gpl-license-in-contemporary-software/ebook/product-21329969.html>.

interaction or dependency of the programs will have to be analyzed. This includes, for instance (in relation to software libraries), whether these are statically or dynamically linked.<sup>101</sup>

It has to be noted however that GPL licenses operate under copyright law, and in many cases, simply using or combining components (even if the combined software is perceived by the end user as a single program) does not produce a “derivative work” according to the applicable copyright law.<sup>102</sup> There have been arguments that combinations with separable add-on program or interface modification dictated by functional requirements do not support a classification as derivative work, as they may be relevant for the program’s functionality (which is not protected by copyright).<sup>103</sup> At least under the US legal system, whether a combination of software creates a derivative work depends on whether the combination (a) is sufficiently permanent, (b) contains significant and creative portions of the program(s), (c) is creative in its own right, and (d) involves significant and creative internal changes to the other program that cannot be easily separated or distinguished from the other program.<sup>104</sup>

The EU Software Directive does not contain a definition of derivative work, but as noted in Chapter 5 makes provision for adaptation for interoperability purposes, providing that adaptation shall not require authorization by the rightholder where they are necessary for the use of the computer program by the lawful acquirer in accordance with its intended purpose, including for error correction.<sup>105</sup> Decompilation is also permitted for interoperability purposes without authorization. As it has been noted that ideas are not copyright protected, expression and the interaction or relationship between the source code of original work and a derivative work is crucial when analyzing the license compatibility of derivatives. It has to be admitted that in reality, it is sometimes difficult to draw the line; however one commonly held view is that exchange of data does not make two pieces of software a derivative work.<sup>106</sup>

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<sup>101</sup> Generally, it is assumed that static linking is one of the marks of a derivative work, while dynamic linking may not be.

<sup>102</sup> [https://joinup.ec.europa.eu/software/page/licence\\_compatibility\\_and\\_interoperability](https://joinup.ec.europa.eu/software/page/licence_compatibility_and_interoperability).

<sup>103</sup> Lothar Determan, ‘Dangerous liaisons – software combinations as derivative works? Distribution, installation, and execution of linked programs under copyright law, commercial licenses and the GPL’, 2006, Berkeley Technology Law Journal, vol. 21:4, pp. 1452-9.

<sup>104</sup> *Ibid*, p. 1455.

<sup>105</sup> Article 5 of the Software Directive.

<sup>106</sup> [https://archive.fosdem.org/2013/schedule/event/european\\_derivative\\_work/attachments/slides/219/export/events/attachments/european\\_derivative\\_work/slides/219/Derivative\\_Work.pdf](https://archive.fosdem.org/2013/schedule/event/european_derivative_work/attachments/slides/219/export/events/attachments/european_derivative_work/slides/219/Derivative_Work.pdf).

### 7.5 Potential implications for CHIC

In collaborative projects such as CHIC, certain license conditions (eg strong copyleft) may restrict the options that are available for use and dissemination of the resulting foreground.<sup>107</sup> These conditions, by infecting the whole infrastructure with a particular copyleft term may for instance, restrict the ability to onwardly license the work (as well as to seek other IP protection such as patent). As the CHIC infrastructure will be made up of different components (software), it will be appropriate to have a matrix of license compatibility to forestall any adverse occurrence. This is indeed also reflected in the requirement of the CHIC consortium agreement, (in clause 9.8.6) that partners should not introduce derivative works governed by copyleft licenses (termed by it ‘controlled’ licenses) as background without the written agreement of all other partners.

Two possible scenarios could be envisaged. The first is where the consortium agrees on specific license(s) under which the foreground (as whole or individual components) will be distributed. If such an approach is taken, then a matrix of compatibility (see table 1 below), showing both upstream compatibility (components that can be merged into a larger work which permits distribution under the intended CHIC license), and downstream compatibility (components that can be merged to the work received under the intended CHIC license) will be kept during the development stage of the project. This will be done through a license audit of potential components to be used in the project once they are known.

Existing licenses	Component	Possibility of distributing the larger application under a specific license		
		Incorporation	Static link	Dynamic link
Apache 2.0				
GPLv3				
BSD				

<sup>107</sup> Such as non-commercialisation of derivatives.

LGPL			
GPLv2			
EUPL			

Table 1: License audit table

In doing this check, the following factors should be taken into account:

1. the license versions of the component
2. whether there is a dual or multiple licenses existing for the component
3. whether there is exception list implemented at license level<sup>108</sup>
4. whether the license and/or the copyright holder allows relicensing under certain circumstances (for instance: it is permitted to relicense the software under a newer version).

As revealed in the WP 4 questionnaire so far, various inbound licenses such as Apache 2.0, GPLv3, BSD, LGPL, and proprietary licenses will be present in developing the CHIC infrastructure.<sup>109</sup> Thus, we are of the view that using or modifying existing programs as well as further aggregating or merging the models (with adaptors, merger, linker) to create hypermodels, will potentially result to derivative works (see figure 1 in chapter 4) necessitating a license audit.

A second scenario will be where no decision is made as to a specific license or where it is impossible to do so, then the foreground has to be distributed as modular software (separate programs/components), where each component could be distributed under a separate license. This option on the other hand, gives individual partners the leverage to choose an appropriate license that suits their purpose (where the particular foreground is attributable to them), such as where they may want to apply for patent of their foreground. In this case, each developer has to ensure internal harmony or compatibility of its developed component.

**Use of commercial or proprietary licenses in CHIC**

<sup>108</sup> EUPL, MySQL, LGPL have such exception list.

<sup>109</sup> As revealed in the answers to WP 4 questionnaire. However, no comprehensive list is available now.

As indicated earlier, at least two of the CHIC partners have indicated that they will use some components under proprietary license.<sup>110</sup> Creating derivatives from such components requires appropriate license permitting modification and distribution of the derived work to forestall future litigation. It is the responsibility of the partner that is bringing such background to obtain the necessary license. Furthermore, where a proprietary license was obtained for developing and testing a program, a clear understanding has to be reached as to who will maintain such license during the exploitation of the foreground - the end user or the partner that has background.

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<sup>110</sup> Ibid.

## 8 Conclusion

Different aspects and sources of IPR including copyright of computer programs, database right, patent, impact of licensing conditions, as well as the use of background and foreground in the project have been considered in this deliverable. Indeed, various constellations are possible when considering the IPR that subsists in a complex work, such as seen in the CHIC infrastructure. Although from a user's perspective, the whole infrastructure may look like a single unit, it is in fact a composite system that bundles many distinct IPR simultaneously. In this regard, one rightholder may have copyright in the published work about a model, while another implementing it into a computer program, would have a copyright separately in the software. The same applies to any other elements of the CHIC infrastructure that contain original computer code (as software), including the underlying system used for running the components.

Concerning the copyright in the models, it has been shown that models in their raw form as ideas per se are not protected by copyright; only the expression of such ideas is protected. In the first instance, the Copyright and the Software Directives protect publication, and the source and object codes of software (once they exhibit originality) developed in the project. Apart from the copyright protection of the model computer program, data stored in the CHIC repositories, and subsequently accessed and used as part of the execution of the hypo and hyper-models, could be subject to copyright protection, or benefit from the sui generis right, where a degree of originality, is shown in presenting and expressing datasets in a database. However, a pertinent question in respect to the accrual of the sui generis right in CHIC will be, whether "there has been qualitatively and/or quantitatively a substantial investment in either the obtaining, verification or presentation of the contents". The answer to this question is crucial, and it will require to be shown in practical terms, that the data provided and stored within the CHIC data database have been further verified concerning their contents apart from the fact that they may have been obtained from various clinical trials. If no such verification is planned, then at this point they will most likely not attract the sui generis right.

The possibility of patenting the foreground(s) of CHIC, is in our view slim as there are several legal and practical hurdles in taking this route for the whole project as discussed in Chapter 5. However, individual partners are not foreclosed in seeking to patent individual works.

The issue of software license compatibility management is also another important but complicated field that has been considered, which has relevance to both the use of the background and exploitation of the foreground of the CHIC project. Depending on how the software is executed, integrated or linked,

licensing conditions (not only from commercial software, but also open source software), may limit what the consortium may or may not do with the derived work. Components with strong copyleft terms may infect the whole infrastructure, resulting in it being licensed onwards under the same terms (which may affect proprietary use of the software). A thorough license audit will be required in this respect to forestall unwanted knock-on effects.

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## Appendix 1 – Abbreviations and acronyms

<i>BSD</i>	Berkeley Software Distribution
<i>CA</i>	Consortium Agreement
<i>CHIC</i>	Computational Horizon in Cancer
<i>CDDL</i>	Common Development and Distribution License
<i>CeCILL</i>	CEA CNRS INRIA Logiciel Libre
<i>CII</i>	Computer Implemented Invention
<i>D</i>	Deliverable
<i>DOW</i>	Description of Work
<i>ECJ</i>	European Court of Justice
<i>EPO</i>	European Patent Office
<i>EPC</i>	European Patent Convention
<i>EUPL</i>	European Union Public Licence
<i>EPL</i>	Eclipse Public License
<i>FP7</i>	Seventh Framework Programme (EU)
<i>FSF</i>	Free Software Foundation
<i>FOSS</i>	Free/Open Source Software
<i>GPL</i>	General Public License
<i>ICT</i>	Information and Communication Technology
<i>IPR</i>	Intellectual Property Right
<i>LGPL</i>	Library General Public License
<i>MPL</i>	Mozilla Public License
<i>OSI</i>	Open Source Initiative
<i>PIMS</i>	Personal Identification Management System
<i>PCT</i>	Patent Cooperation Treaty
<i>RDF</i>	Resource Description Framework
<i>SaaS</i>	Software as a Service
<i>TRIPS</i>	Agreement on Trade-Related Aspects of Intellectual Property Rights

*UNESCO* United Nations Educational, Scientific and Cultural Organization

*VPH* Virtual Physiological Human

*WIPO* World Intellectual Property Organisation

*WCT* WIPO Copyright Treaty

*WPPT* WIPO Performances and Phonograms Treaty