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The intellectual property of medical data: copyrights to patients' records and database rights to biobanks? [1]

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Introduction

As well as accurate information on the patient is crucial to prescribe adequate treatments, information on humans' biology is essential to develop efficient health care. Notwithstanding the indispensable character of this information, intellectual property is increasingly put forward when discussing the control, the use or the transmission of medical data.

Intellectual property aims at protecting the production of the human creativity and inventiveness. The fundament of such property is to reward the intellectual creation by granting monopolistic and exclusive rights thereon. Intellectual property rights are also set forth as incentives for innovation. They are therefore not meant to protect what already exists without human intervention. Accordingly, mere information describing what exists may not be protected by such rights.

Considering that medical data may be defined as sheer information on the human body, one could wonder whether, at first sight, intellectual property has

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anything to do with it. However, whereas mere information may not be "appropriated" by way of intellectual property rights, any form that integrates, or even compile, such information could be. Furthermore, it is sometimes difficult to trace the border line between information and its setting up, or even to separate one from the other [2].

Two types of medical data, gathered within two types of compilation forms, will be addressed: patients' records and biobanks. Correspondingly, two intellectual property rights could potentially protect these information sources: copyrights and database *sui generis* rights. This explains the division of this contribution in two parts.

The first aim of this contribution is to analyse the likelihood and possible extent of these intellectual property protections to medical data. The second aim is to address the consequences of such protection, bearing in mind the diversity of interests that are at stake and which generally gives rise to conflicts of rights or ethical issues.

The outcomes of the research performed with medical data or on the human body may be, on certain conditions, protected by patents [3]. However, this topic will not be tackled in this contribution.

I. Copyrights to medical records

The medical record is an essential source of information on a patient's health status. This record is inherently bound to the patient and to the medical practice, and is primarily governed by medical law. The data gathered in such record qualify also as sensitive personal data pertaining to the patient: it is therefore also usually addressed by legal practitioners from a privacy point of view [4].

Even if medical data relate to patients and are moreover protected by very strict data protection and secrecy rules, this information is nonetheless "created", sorted, structured, explained and, more generally, processed by professional practitioners and medical administrations. Given this processing of the data and the drafting of reports concerning the health condition of the patients, one could assume that these

CH. CARON, *Droit d'auteur et droits voisins*, Paris, Litec, 2006, p. 63-64.

Biotechnological inventions have been the subject matter of legal developments on European level. See the Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions, *OJ L* 213, p. 13-21.

In this regard, see for example the Working Document n° 131 of the art. 29 Data Protection Working Party on the processing of personal data relating to health in electronic health records (HER), 15 February 2007, n° 00323/07/EN, available at http://ec.europa.eu/justice_home/fsj/privacy/docs/wpdocs/2007/wp131_en.pdf.

intellectual efforts should be worth some legal protection. Copyrights are usually considered in such cases.

A. Possible existence of copyrights to patients' records items

From the point of view of an intellectual property lawyer, the patient's record may be addressed as a bundle of "works" of different natures. Firstly, we have the record itself, namely the written document drafted by the practitioner, which mentions the evolution of the patient's health state as well as the prescribed cares. Then, we have all the attached files, documents and/or other recordings that result from different analyses or diagnoses that the patient has undergone. For example, one could think of cardiographs or any other "graphs", X-rays or any other pictures, endoscopies or any other visual recordings, lab results, and in general, any other item that illustrates or describes the patient's health condition.

Each one of these items could possibly qualify as a "work" and be somehow protected by exclusive copyrights on certain conditions (section 1).

Some particular items may also possibly qualify as "films" (or even "phonograms") and accordingly benefit from neighbouring rights (section 2).

1. Traditional copyright protection

Copyright is a free and automatic protection that is granted, without any formality, on literary and artistic works that are expressed in a certain form [5] and are original.

(a) *A literary and artistic work expressed in a specific form*

Copyright protects "literary and artistic works". This expression is broadly defined and includes "every production in the literary, scientific and artistic domain, whatever the mode or form of its expression may be, such as books, pamphlets and other writings; lectures, addresses, sermons and other works of the same nature; [...]; cinematographic works to which are assimilated works expressed by a process analogous to cinematography; works of drawing, painting, [...]; photographic works to which are assimilated works expressed by a process analogous to photography; [...]; illustrations, maps, plans, sketches and three-dimensional works relative to geography, topography, architecture or science" [6]. This list is not exhaustive, and unclassified works may also be protected [7].

Art. 2 of the Berne Convention for the Protection of Literary and Artistic Works adopted on 9 September 1886 and last revised on 28 September 1978 (hereunder referred to as the Berne Convention).

Art. 2, 1) of the Berne Convention.

D. VAVER and P. SIRINELLI, *Principles of Copyright*, Geneva, W.I.P.O., July 2002, p. 67.

At first sight, any of the above-identified elements of patient's records should qualify as one of the different categories of "literary or artistic work" here above mentioned such as writings (the patient file or any other written work such as notes, comments, etc.), photographic works (e.g. X-rays), illustrations (graphs, cardiograms, etc.), and even cinematographic (audiovisual) works (endoscopies for instance). Furthermore, as a lot of professional sectors, the medical field has been broadly computerised. A medical record is usually part of an electronic patients database, or may even be presented as a small separable database pertaining to a particular patient. Such database, as any compilation of data, could also possibly be protected by copyrights [8].

The embodiment of the work in a form is the first step towards copyright protection: copyright is granted at the moment of the expression of the work into a tangible, or at least perceptible, form. This entails an expression in words, actions, sounds and/or any other tangible or visible materials. This condition specifies also the subject matter of copyright: this legal protection only extends to the form of the work, and not to the underlying ideas, concepts or information [9]. As regards scientific works, copyright will never protect facts, figures, information, theories, discoveries or other scientific knowledge that are used or described in the text: only the latter will be protected against the mere plagiarism of its structure and/or wording. In other words, copyright never allows an author to oppose the rewriting of the same information in another text, using a different structure as well as other wording and expressions [10].

Applied to the patient's record, this rule has for important consequence that nobody could claim any copyright on the substance of medical data as such. No one could monopolise such data, which only constitute the reflection of existing facts pertaining to the patient's condition.

Finally, one should also mention that copyright does only protect creations that emanate from the human mind and are the result of human activity. One could not pretend having copyrights on something one has discovered in the nature, even if such thing was unknown until such discovery. Likewise, works that are the result of

8 Databases may also be protected by *sui generis* rights, which are analysed in the second part of the present contribution. At first sight, should a patient's record qualify as a database in the sense of this specific legislation, such database could also be granted *sui generis* rights, on condition that substantial investments in its creation have been made. Should the investment made in the record be substantial, one should therefore identify the "producer" of such database. In such situation, the difficulties to identify its "producer" would be of the same nature as the ones encountered as regards the producers' rights on the first fixations of phonograms or films (cf. *infra*).

9 In this regard, one usually says that ideas and information are "free".

10 See in general, X. STRUBEL, *La protection des œuvres scientifiques en droit d'auteur français*, Paris, CNRS Editions, 1997.

sheer chance, of mere animal activity or of purely automatic processes may not qualify for copyright protection [11].

This also has some implications as regards certain specific items of the patient's record, as the use of totally automatic machinery becomes more and more frequent in medicine. One cannot pretend having created a "work" when referring to the result obtained by making a patient enter into a machine and by pressing a button. However, when the outcome was obtained with the real intervention of a practitioner, who made some personal choices as regards the utilisation of the machine and the results obtained, it could qualify as a "work" under copyright law.

(b) *An original work*

In order to be copyrighted, it is not sufficient that a patient's record item be created by human intervention and qualify as a "work": it must furthermore be original. There is no uniform international, neither even European, definition as to this concept of "originality". The definition of an original work differs slightly from one country to another and, moreover, there is a traditional division between civil law countries and common law countries e.g. the United Kingdom [12]. In civil law countries (such as Belgium or France), the originality criterion means that the work should "bear the mark of the personality of its author" [13]. The notion implies therefore a minimum of creativity. The common law systems generally require a lower standard of originality [14]: it only implies that the work must originate from the author, who should have expended "skill, judgement and/or labour" on its creation. This criterion entails that the author's input must satisfy a certain minimum standard of effort [15].

Whereas there is no European uniformity as for the originality notion in general, one must however notice that several directives define the concept as to specific works, namely photographs [16], databases [17] and computer programs [18]. Article 6 of the Directive 2006/116/EC reads for example: *"photographs which are original in the sense that they are the author's own intellectual creation shall be protected in accordance with*

11 See for example, CH. CARON, *op. cit.*, p. 48-51.

12 J.A.L. STERLING, *World Copyright Law*, London, Sweet & Maxwell, 1998, p. 254-267.

13 A. LUCAS and H.-J. LUCAS, *Traité de la propriété littéraire et artistique*, 3rd ed., Paris, Litec, 2006, p. 71-87; A. STROWEL, "L'originalité en droit d'auteur, un critère à géométrie variable", *J.T.*, 7 septembre 1991, p. 513-518.

14 D. VAVER and P. SIRINELLI, *op. cit.*, p. 30.

15 W.R. CORNISH, *Intellectual Property*, 5th ed., London, Sweet & Maxwell, 2003, p. 388.

16 Art. 6 of the Directive 2006/116/CE of the European Parliament and of the Council of 12 December 2006 on the terms of protection of copyrights and certain related rights (codified version), *OJ L* 372, p. 12-18.

17 Art. 3(1) of the Directive 96/9/EC of the European Parliament and of the Council of 11 March 1996 on the legal protection of databases (referred to as "Database Directive"), *OJ L* 77, p. 20-28.

18 Art. 1(3) of the Directive 91/255/CE of the Council of 14 May 1991 on the legal protection of computer programs, *OJ L* 122, p. 42-46.

Article 1 [i.e. as "works" within the meaning of Article 2 of the Berne convention]. *No other criteria shall be applied to determine their eligibility for protection. Member States may provide for the protection of other photographs"*. Recital 16 of the same Directive specifies that a picture is original if it is its author's own creation "*reflecting his personality*", which adds a subjective dimension to the definition. Even if such definition is only provided as regards certain categories of works, one could wonder whether the criterion of originality expressed as "the author's own intellectual creation" should not be considered as the European standard [19].

In any legal system, the originality condition entails that the author should at least have a breathing space allowing him to choose the way he expresses himself and gives form to the work. When there are no alternative ways to write this information or data, this means that the expression of these information and data is not original and, therefore, not copyrighted. In such case, one usually says that the expression is merged with the idea it is meant to express (merger doctrine) [20].

In the same sense, the expression of the work should not be dictated by external factors. These external factors may be purely technical: in such case, it is impossible to influence the result as it is due to the technical mean that was used. For instance, the fact that X-rays are in black and white is not due to the choice of the practitioner, but to the technique that is used: it is therefore not an original element of the shot. Other considerations that are not purely technical may also constitute such external factors, such as the intrinsic purpose or nature of the work, the professional state of the art, or even obviousness (*scènes à faire* doctrine) [21].

These rules and doctrines will generally have special importance as regards each item of the patient's records.

Medical codes of ethics, medical law or patient rights regulations usually provide for a minimal content as regards patients' records [22]. This content encompasses identification data (name, contact details, birth date, sex, profession), date, diagnosis and prescribed treatment for each visit, date and results of medical exams, urgency data (allergies, pathologies, etc.) and, in general, any information that could prove to be useful in order to complete a diagnosis and carry on an efficient treatment. At first sight, the above data could be considered as pure information falling outside copyright protection. Furthermore, the presence of such information in the record is not due to the choices made by the practitioner, but is imposed by law and/or professional ethics. The disposition of such information shall generally be imposed by logic, effectiveness purposes and/or the professional state of the art [23]. A medical file that only consists of a compilation of this information, which would most often be the case, should therefore not be granted any copyright protection. However, one could imagine some particular situations where a practitioner has completed the record with some personal comments or analysis written in a more elaborated or literary form that could prove to be original, and therefore, capable of being copyrighted. One could also imagine that the way this information is presented on the paper record (colours, columns, tables, etc.) could be copyrighted.

19 J.A.L. Sterling, *op. cit.*, p. 267.
20 J.A.L. Sterling, *op. cit.*, p. 250-253.
21 *Ibidem.*
22 See for example Ph. Biclet, "Le dossier médical dans tous ses états", *Médecine et Droit*, 2006, n° 81, p. 174-175; I. Lutte, "Le dossier concernant le patient" , in *Actualités de droit médical*, Bruxelles, Bruylant, 2006, p. 101-147.

The aim of an X-ray is to provide a two-dimensional representation of a body part under the best angle possible: the practitioner shall therefore apply the technique he learned, improved and is still improving in order to obtain a shot that reaches this objective. In other words, such type of work has for only goal to slavishly depict reality [24]. In such circumstances, one therefore realises that between the state of the art, the purpose of the work and the technique that is used, the practitioner does not have a lot of freedom space to make personal choices [25]. Such appreciation shall however, as explained above, differ from country to country. For example, some authors seem not to doubt that mammographs are copyrighted under the UK Copyright, Design and Patents Act of 1988 [26].

2. Neighbouring rights on particular records' items: protected films or even phonograms?

Besides the protection that is granted to the authors on their original works, some international and national lawmakers have decided to grant other specific rights on certain works in order to protect the investments made in their creation, and more particularly, their *first fixation*. Accordingly, films [27], as well as phonograms, benefit

23 One assumes that the good way of drafting a medical file is taught to medicine students or at least to trainees in the general frame of the knowledge transmission from generations to generations.
24 M. Buydens, *La protection de la quasi-création*, Bruxelles, Bruylant, 1993, p. 186-192.
25 "With photographic works, the skill required to produce the final picture may only be the simple manual operation of the operating a shutter or pushing a button". S. Ricketson and J.C. Ginsburg, *International Copyright and Neighbouring Rights*, Oxford University Press, 2nd ed., 2006, p. 443.
In the field of photography, Belgian case law has already acknowledged copyrights to pictures for the making of which the photographer made the following choices: lightning, exposure time, background, film quality, lens, angle of the shot, the instant the shot is taken, etc. See for example E. Cohez, "Fotografie en auteursrecht", Die Keure, 2006, p. 39-40 (and the cited case-law).
26 G. D'Agostino, Ch. Hinds, M. Jirotka, Ch. Meyer, T. Piper, M. Rahman and D. Vaver, *IP Rights in Medical Data in a Grid Environment (IMaGE): Challenges to Copyright Law*, the First International Conference on Legal, Security and Privacy Issues in IT (LSPI), 2006; see also *On the Importance of Intellectual Property Rights for e-Science and the Integrated Health Record*, from the same authors, Integrated Healthcare Workshop, Edinburgh, 2006.
27 "*Videogramme*" in French Law – see art. L 215-1 of the French code of intellectual property law.

from neighbouring rights (rights existing beside copyrights, or "related rights"), which are granted to their producers. Like copyrights, these related rights are acquired freely and automatically.

In the European Directive on certain rights related to copyrights in the field of intellectual property [28] a film is defined as, *"a cinematographic or audiovisual work or moving images, whether or not accompanied by sound"*. Any sequence of animated images would qualify as a "film" no matter on what the work is recorded or saved (tape, dvd, cd, numeric file, etc.) [29].

According to the Rome Convention [30], *"phonogram means any exclusively oral fixation of sounds of a performance or of other sounds"*. Article 2, b) of the WIPO Performances and Phonograms Treaty [31] further specifies that these performances or sounds must be fixed "*other than in the form of a fixation incorporated in a cinematographic or other audiovisual work*". Article 2, c) of the same Treaty defines "fixation" as "*the embodiment of sounds, or of the representations thereof, from which they can be perceived, reproduced or communicated through a device*". The definition of phonogram is therefore not influenced by the used media.

Contrary to copyrights, these neighbouring rights are granted whether or not their objects (film or sound recording) are original [32]. Therefore, in order to be granted the protection, the only condition that has to be met is to qualify as 'film' or as 'phonogram'. Given their broad definition, one may easily figure out the importance that could be given to such rights as regards recorded elements of the patient's records. 'Endoscopies' for example could qualify as 'films'. Likewise, one could imagine the need to record the heartbeats of a patient on a tape: this could be a 'phonogram' in the sense of the law.

One must stress the importance of the identity of these rights' owner. Indeed, contrary to copyrights (which are granted to the authors of the protected work), the analysed neighbouring rights are granted to the "producers" of the first fixation of films or phonograms. The "producer" could commonly be defined as the person who, or the legal entity which, takes the initiative and has the responsibility for the

28 Art. 2, c) of the Directive 2006/115/EC of the Parliament and of the Council of 12 December 2006 on rental right and lending right and on certain rights related to copyright in the field of intellectual property (codified version), *OJ L* 376, p. 28 – 35; see also article 3, § 3 *in fine* of the Directive 2006/116/CE, *op. cit.*

29 F. Brison, *Het naburig recht van de uitvoerende kunstenaar*, Brussels, Larcier, p. 250.

30 Art. 3, b) of the International Convention for the Protection of Performers, Producers of Phonograms and Broadcasting Organisations, done at Rome on October 26, 1961.

31 Wipo, Performance and Phonograms Treaty adopted in Geneva on December 20, 1996 (here under WPPT).

32 J. Reinbothe and S. Von Lewinski, *The EC Directive on Rental and Lending Rights on Piracy*, London, Sweet & Maxwell, 1993, p. 52; Brison, *op. cit.*; A. Lucas and H.-J. Lucas, *op. cit.*, p. 629; F. De Visscher and B. Michaux, *Précis du droit d'auteur et des droits voisins*, Bruxelles, Bruylant, 2000, p. 289-293.

first fixation of the sounds or the films [33]. This notion has to be construed bearing in mind the *rationale* of neighbouring rights: they are meant to protect the (presumably high and risky) investments particularly required for the production of phonograms and films [34]. The producer is not the person who handles the camera or the microphone, but rather the one who takes the initiative of an investment or an undertaking [35]. Undertaking and investments are therefore the two elements that have to be considered as to the identification of the neighbouring rights' owner.

When applying these principles, the determination of the "producer" of medical filmed sequences or sound records may quickly become tricky. Let's take 'endoscopies' for example. These "films" are created thanks to costly machines, which are generally acquired by practitioners or their hospital: this investment is far more important than the one needed for each time the machine is used to make a short film relating to a particular patient. Furthermore, should one solely take into consideration the disbursements made for the specific shot, one neither clearly determine who makes such investment. Indeed, the practitioner who takes the shot should normally be reimbursed by the patient for such service. The latter may also, in some cases, be totally or partly refunded by his social security or health insurance. The question pertaining to the identity of the "film" producer, seen as the investor, could somehow be thorny. While the investment criterion seems blurring in the current case, the "initiative" criterion may be more determining. In the current case, given the patient's "self determination" principle [36], we would be inclined to think that the patient has to be considered as the person who takes the initiative (the decision) to undergo such analysis. According to this criterion, the patient would therefore finally be considered as the original owner of such related rights. However, such conclusion could vary from one case to another. One could even imagine situations of "co-production", and therefore, of "co-ownership", which would not simplify the situation.

B. Extent of protection and potential conflicts with privacy rights or medical law rules

According to the analysis we made above, we have to conclude that some parts or items of a patient's record could sometimes and somehow be protected by copyrights and/or related rights. Some of these rights are likely to be the ownership of medical practitioners (as "authors" of such materials) or of their medical institutions

33 See for example art. 4, d) of the WPPT; art. L 215-1, §1, of the French code of intellectual property law.

34 See recitals 7 and 8 of the Directive 1992/100/EC of the Parliament and of the Council of 1 November 1992 on rental right and lending right and on certain rights related to copyright in the field of intellectual property, *OJ L* 346, p. 61-66.

35 F. De Visscher and B. Michaux, *op. cit.*, p. 290; A. Lucas and H.-J. Lucas, *op. cit.*, p. 630.

36 Cf. *infra*.

(as copyright assignees, or as "producers" or "co-producers" of first fixations of phonograms or films) [37].

The owners of copyrights or related rights normally benefit from some exclusive rights on the protected material. This legal protection grants their owner the rights to authorise or forbid the reproduction (including modification, translation, digitalisation, etc.), the distribution or the communication (by any means, including by way of Internet) of these materials to the public [38], unless one of such acts is covered by a right's limitation. Furthermore, on the basis of his "moral" copyright, an author has the right to agree or not with the divulgation of his work, to claim for credits and to oppose any modification.

Accordingly, a practitioner or a medical institution, which would be in a position to claim copyrights or related rights on a patient's record would be entitled to exclusive rights to control the reproduction and the communication of the record. One must however bear in mind the particularities of the information embodied in the "work", and of the special relationship that exists between the "author" and the patient, and between the data and their subject. Those specificities have an important influence before and after the creation of the "work" and its protection through copyrights.

1. A patient-practitioner relationship and data processing preceding the creation of copyrighted works

The work is created with data relating to the patient, his body, his health and the treatment he undergoes. These data are subject to very strict sensitive data protection and privacy rules [39]. Furthermore, they are collected in the framework of a practitioner-patient relationship, which is governed by professional ethics and secrecy rules [40]. Even before creating the work, the practitioner is bound by those rules and must respect the special nature of the data. Accordingly, except in specific cases, the processing of the data may, in general, only occur with the agreement of the patient. Furthermore, such processing may only occur conforming to the announced purposes of the processing, to the law in general and therefore, amongst others, to fairness and proportionality principles [41].

37 We will not address in this contribution the questions pertaining to rights' ownership, which could be quite complex and differing from country to country. On this topic, see for example S. RICKETSON and J.C. GINSBURG, *op. cit.*, p. 357-398.

38 Traditionally, a communication is public when it does not remain in the circle of close family.

39 In this regard, a general reference is made to the other contributions to this book.

40 *Ibidem.*

41 We refer for example to art. 6 of the Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data (hereunder referred to as the Data Protection Directive), *OJ L* 281, p. 31-50.

Actually, the creation of a copyrighted work with the data may be analysed as being part of their processing. Indeed, the creation of such copyrighted work implies that the needed data are collected, recorded, stored, etc. [42]. Accordingly, the mere creation of the work is only possible thanks to the will of the patient to choose a practitioner, to communicate to this latter his personal data and to agree to their processing.

As a preliminary question, one could wonder whether the patient's agreement to record his personal data extends to the matter of creating a "copyrighted" work with them included, and if claiming copyrights on such a file would be a fair behaviour towards the patient. As copyrights are granted freely and automatically by law, one could not impose to practitioners to "avoid" creating a copyrighted work (one could not refrain practitioners from creating works), but a practitioner may decide not to enforce such copyrights. The question is therefore only relevant when the practitioner decides to claim and enforce his copyrights, especially when this is done against the will or the interests of the patient. In such circumstances, one could argue that such behaviour does not respect the obligation of the practitioner to fairly process the data or to do it in conformity with the announced purposes of the processing.

2. Medical data do not lose their protection when incorporated in a copyrighted work

The fact of creating a copyrighted work will never modify or alter the nature of the data, and the same privacy, secrecy and data protection rules will apply to the copyrighted work. This will directly affect the normally "exclusive" character of copyrights.

According to the positive definition of copyrights, the author is the sole person entitled to authorise the publication and public communication of his work. However, the practitioner will not be the sole person to decide when, how and whom the record will be reproduced for or communicated to. Those acts will not be allowed without the prior consent of the patient, and in general, all the rights a patient could claim with respect to a 'traditional' record should also be recognised to him as regards a 'copyrighted' one. The author should therefore never communicate or reproduce the work, or authorise such acts without the authorisation of his patient, unless he does it in a way that does not infringe his professional ethic,

Art. 1, 2 (b) of the Data Protection Directive: *" processing of personal data ("processing") shall mean any operation or set of operations which is performed upon personal data, whether or not by automatic means, such as collection, recording, organization, storage, adaptation or alteration, retrieval, consultation, use, disclosure by transmission, dissemination or otherwise making available, alignment or combination, blocking, erasure or destruction".*

his secrecy obligations and the laws on personal data protection. In practice, it means that he will almost always need, at least, the permission of his patient.

The negative side of copyrights entails that the author may forbid the publication and the communication of his work. Could a practitioner, invoking his copyrights, oppose the communication to, or the reproduction made by colleagues, medical institutions or even his patient himself? In other words, knowing that his practitioner could have some copyrights on his record, should the patient ask the permission of this author in order to reproduce or communicate the work to somebody?

3. Copyrights vs. the patient's right to access to and receive a copy of his record

First of all, one must stress that in general, the patient's minimal rights encompass a right to access his record and to get a copy of it [43]. Where some costs may be charged to the patient for exercising his right to get a copy, these costs would only cover the administrative and/or material disbursements [44], and should in no way include copyright "royalties". Whereas the right to access a work is not as such recognised as being part of the exclusive rights of the author (this is actually a debated issue), the right to receive a copy of the record clearly departs from the author's exclusive "copy"-right to reproduce the work. One could indeed not imagine another situation where somebody could have the right to ask an author the delivery of a free copy of his work [45].

This particular rule concerning the right of the patient to receive a reproduction of his record should be deemed taking precedence over the general rule providing exclusive reproduction rights to the author on his work. Indeed, such derogation to copyright principles has to be addressed as a specific law that derogates the general

43 See for example TH. CASAGRANDE, "L'accès direct au dossier médical: principes juridiques et réalités pratiques", *Médecine & Droit*, 2005, p. 50-54; M.-N. VERHAEGEN, "L'accès du patient au dossier géré par le patient professionnel", *Rev. Dr. Santé*, 2003-2004, p. 74-93; D. MANAI, *Les droits du patient face à la médecine contemporaine*, Helbing & Lichtenhahn, Genève, 1999, p. 228-236.

44 For example, art. 9 of the Belgian Act of 22 August 2002 pertaining to the patient's rights (*M.B.*, 26 September 2002) provides for the right of the patients to consult and get a copy of their file. Originally, the Act authorised the practitioner to charge their clients a fee that would "cover their costs". Given the problems faced in order to assess such costs, this law was modified by the Act of 13 December 2006 (*M.B.*, 22 December 2006), which empowers the King to fix the amounts by way of a royal decree. The Royal Decree of 2 February 2007 (*M.B.*, 7 March 2007) provides that the maximal cost for a text copy on paper is 0,10 EUR per sheet. The "price" for any copy pertaining to medical pictures may not be higher than 5 EUR per image. Numerical copies may be gathered on a numerical media: the "price" of such copies may not be higher than 10 EUR. Finally, the "price" of a copy of the whole record may not exceed 25 EUR.

45 Art. 455 of the Dutch Medical Treatment Act (Wet op de Geneeskundige Behandelingsovereenkomst) of 1994 even provides that the patient has the right to demand the destruction of his record, what could be analysed as an outstanding derogation to the moral copyrights (integrity right) of the author of this file.

copyright law [46]. Furthermore, this usually stays in line with the principle according to which more recent law prevails over an inconsistent earlier law [47].

The patient should therefore in any case be allowed to get a copy of his record. But could his use of such copy be hindered by copyrights enforcement?

Once in possession of a copy of his record, according to copyright rules and related limitations, the patient could only make private copies and communicate the work privately (usually, only within his close family circle).

Accordingly, from a strict copyright prospective, the patient could not, *in contrario*, communicate his record to anybody outside his close family without the author's consent. One could already underline that patients have generally the right to access their record directly or with the intermediary of another medical practitioner (or even sometimes of another trusted party) [48]. One may therefore see in such provision another legal derogation to copyrights allowing the communication to another person than the patient himself and who might not be inside his close family circle.

Outside the application of such derogations, one could imagine some practitioners or health institutions might not allow their patients to communicate their records' copy to competitors in order to restrain their clients from going elsewhere, or at least, try to sell such transfer.

This idea is quite appalling and such deviant use of copyright could instinctively be deemed abusive and unethical. Moreover, such practice would seem to be infringing some fundamental rights of the patient, amongst which his right to self-determination.

4. Copyrights vs. the patient's right of self-determination

In relation to the patient's right to access his record, one has frequently put forward the idea of the patient's property right to this record [49]. During a period of time, the French public health code provided explicitly that the patient was "the owner" of his record [50]. This concept has been debated. Some authors are intent to make a link between the ownership of the record and the ownership of one's own body,

46 *Lex specialis derogat generali*.

47 *Lex posterior derogat priori*: laws about the access rights of patients are usually more recent than copyright laws.

48 See for example art. 9 of the Belgian Act of 22 August 2002 or article L1111-7 of the French code of public health.

49 See the description of such theory in Y. POULLET, "A propos de la "propriété" du dossier médical... Quelques considérations autour des notions de propriété, droits subjectifs et intérêts", *Eigendom – Propriété*, Bruges, Die Keure/La Charte, 1996, p. 301-319; see also on this topic SCHUTYSER, "Eigendom en medisch dossier", *R.W.*, 1983-1984, p. 3022-3048.

50 Art. L145-6 of the French code of public health, repealed and replaced by article L1111-7, which does not contain such provision anymore.

which is an idea that is, as such, strongly criticised [51]. Some other authors describe the access right as a kind of right *in rem* or an intellectual property of the patient on the data relating to him [52]. Whereas it is difficult to accept the existence of a right *in rem* relating to immaterial and abstract subject matters such as information, we do not back up the idea of the patients' intellectual property on their data, as all intellectual property rights are provided for in order to protect the results of the human intellect's work, namely the "intellectual works". Therefore, one may not easily accept to grant somebody an intellectual property on pure data relating to the nature and the actual condition of his own body. Finally, some authors compared the access right to an outstanding information right, which is inseparable and necessary to the exercise of another patient right, namely the right of free and self-determination [53]. This right confirms the autonomy of the patient in the caring for his health, and its corollaries are the free choice of practitioners and the liberty to change practitioners at any time [54]. As well as the author may not oppose the patients' right to attain a copy of his record, he may therefore not oppose the communication of this record to a competitor, nor the modification and reuse of such record by this competitor in the framework of the continuance of the patient's cares, for this would breach the patient's fundamental right to self-determination. Indeed, one could not figure out arguments that could induce the prevalence of a diverted application of copyright law over fundaments of health law and of the right to respect for private life.

C. Intermediary conclusion

Even if in some special and rare cases, practitioners or medical institutions could possibly own some copyrights to certain elements of the records they created, the general rule should be that those copyrights could never be used in order to distort the patient's rights.

In these rare cases, one could wonder in which circumstances and towards whom this practitioner could actually enforce his copyrights. At first sight, one could put forward that the copyrights of the practitioner could be enforced in cases whereby

51 X. DIJON, *Le sujet de droit en son corps – une mise à l'épreuve du droit subjectif*, Thèse, Travaux de la Faculté de Droit de Namur, n° 13, 1982, p. 662 *et seq.*

52 P. CATALA, "Ebauche d'une théorie juridique de l'information", *Rev. dr. Prospectif*, 1980, p. 183. See also on this topic Y. POULLET, "Le fondement du droit à la protection des données nominatives: 'propriété ou liberté'", *nouvelles technologies et libertés: actes du colloque tenu à la faculté de droit de Montréal, les 9 et 10 novembres 1989*, Litec, Paris, 1991, p. 175 *et seq.*

53 The access right is usually depicted as a consequence of this ground principle of self-determination right. See D. BERTIAU, "Comprendre le principe d'autonomie en droit de la santé", *Médecine & Droit*, 2006, p. 58; D. MANAI, *op. cit.*, p. 228.

54 Y. POULLET, *op. cit.*, p. 308.

some use of the record is done by the patient or with his consent, and when this use is not protected or covered by one of his patient's rights. One could for example think of the case when, for a reason or another, the patient would decide to publish all or part(s) of his medical record. One could also think of cases when only some copyrighted materials, that would not encompass any medical data, were extracted from the record (a copyrighted lay out for example) and reused in some ways that are covered by the exclusive rights of the author.

II. Database rights on biobanks

Biobanks [55] are collections of data which have become essential tools of research in the development of treatments to cure the human being. To fulfil this general objective, biobanks' creators need to collect, sort and structure donors' human tissue and personal data [56]. Due to the fact that these data relate to individuals, they could qualify as protected personal data and data protection law may therefore apply. The above-mentioned operations which are inherent to the start up and maintenance of any biobank would therefore have to comply with data protection rules.

Notwithstanding the application of data protection rules, biobanks, as any compilation of data, shall most probably attract some intellectual property rights protection, especially database rights [57]: copyrights and the European *sui generis* rights. While

55 Some examples of biobanks which are already operational or under construction: the CARTaGENE Project, the Estonian Genome Project, the UK Biobank, the Latvian Genome Project, the GenomEUtwin Project, the HapMap Project, the PharmGKB, the Singapore Tissue Network, the Biobank Japan, deCODE Genetics or the Banco Nacional de ADN.

56 A biobank may be constituted on the basis of data and samples collected from patients or other donors. "Donor" will be used as a generic term gathering patients and any other type of persons whose data and samples are gathered in the biobank.

57 Literature concerning the database rights: B. WARUSFEL, "La protection des bases de données en question: un autre débat sur la propriété intellectuelle européenne", [octobre 2004] 13 *Propriétés intellectuelles*, p. 896-906; N. THAKUR, "Database Protection in the European Union and the United States: The European Database Directive as an Optimum Global Model?", [2001] 1 *I.P.Q.*, p. 100-133; M. BUYDENS, "Le nouveau régime juridique des bases de données", [1999] *I.R.D.I.*, p. 4-12; P.B. HUGENHOLTZ, "Implementing the European Database Directive", *Intellectual Property and Information Law, Essays in Honour of Herman Cohen Jehoram*, The Hague/London/Boston: Kluwer Law International, 1998, p. 183-200; N. MALLET-POUJOL, "La directive concernant la protection juridique des bases de données: la gageure de la protection privative – The directive concerning legal protection of data bases: attempting the impossible dream of appropriation", *Computer & Telecoms Law Review* 1996/1, p. 6-16; J.-L. GASTER, "La nouvelle directive européenne concernant la protection juridique des bases de données", *Ae&M*, 1996, p. 187-192; L. KAYE, "The Proposed EU Directive for the Legal Protection of Databases: A Cornerstone of the Information Society?", [1995] 12 *E.I.P.R.*, p. 583-588; S. CHALTON, "The Amended Database Directive Proposal: A Commentary and Synopsis", [1994] 3 *E.I.P.R.*, p. 94-100; J. HUGHES and E. WEIGHTMAN, "EC Database Protection: Fine Tuning the Commission's Proposal", [1992] 5 *E.I.P.R.*, p. 147-150.

copyright protects the skeleton ("structure") of the biobank, *sui generis* rights aim at protecting, to a very defined extent, its content.

The classical "copyrights" that might protect the structure (or skeleton) of the biobank will not be analysed hereunder, as they should not regard the data as such [58]. The database *sui generis* rights shall be the main topic of this second part of the contribution.

A. Biobanks are databases

1. Databases' definition

A first definition of databases [59] may be found in the Berne Convention [60], which describes them as *"collections of literary or artistic works such as encyclopaedias and anthologies which, by reason of the selection and arrangement of their contents, constitute intellectual creations"*. This "strictly copyright-oriented" definition is rather restrictive and its drafting is not adapted to the current development of our information society. The Berne Convention provides that such intellectual creations "*shall be protected as such, without prejudice to the copyright in each of the works forming part of such collections*". From the reading of this provision, one may realise that a database may consist of a compilation of copyrighted works and that such compiling does not prejudice the related copyright. By analogy, and in general, database rights are without prejudice to any other protection that could apply on the data, such as copyright, patents, trade marks, design rights, for example. This rule also applies to privacy rights that may protect individuals' data integrated in the database [61]. One must also stress that, contrary to the letter of the provision, the content of a protected database is not limited to "literary or artistic works".

This principle has been confirmed in other international copyright treaties, which expressly extent the content of databases to any other material. Indeed, article 10(2) of the World Trade Organisation's (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights [62] (TRIPS Agreement) of 1994 provides that "*compilations of data or other material, whether in machine readable or other form, which by reason*

58 We refer to the first part of this contribution.

59 For an analysis of the notion of "database", see M. VIVANT, "Recueils, bases, banques de données, compilations, collections…: l'introuvable notion? À propos et au-delà de la proposition de directive européenne", *Recueil Dalloz Sirey*, 1995, 26 cahier – chronique, p. 197-200. See also E. DERCLAYE, "What is a Database? A Critical Analysis of the Definition of a Database in the European Database Directive and Suggestions for an International Definition", *The Journal of World Intellectual Property*, [2002] 5 (6), p. 981-1011.

60 Art. 2, 5) of the Berne Convention.

61 See recital 48 of the Database Directive.

62 The TRIPS Agreement embraced the principles settled by the Berne Convention, added some obligations and clarified some Berne requirements. S. RICKETSON and J.C. GINSBURG, *op. cit.*, p. 158.

of the selection or arrangement of their contents constitute intellectual creations shall be protected as such. Such protection, which shall not extend to the data or material itself, shall be without prejudice to any copyright subsisting in the data or material itself". The World Intellectual Property Organisation's (WIPO) Copyright Treaty [63] has adopted the same approach as well.

The European Directive 96/9/EC on the legal protection of databases (hereunder referred to as the "Database Directive") has consecrated the following definition of databases: *"collections of independent elements, including artistic, literary, musical works, texts, data or other materials arranged in a systematic way and individually accessible by electronic or other means"* [64]. This definition is very precise. It does not only refer to the different natures of the items that can compose a database, but also to the means of accessing them and to the requirement of "individual accessibility". This means that each item must be accessible independently from the set of elements gathered in the database. The criterion of independency entails the exclusion of some compilations, like books for example, whose content's items are generally not independent one from another. The regime of protection is not part of the definition, for this directive provides for two different regimes, namely copyright and *sui generis* rights. The regime of copyright is the same as the one referred to in the above mentioned texts. The essential innovation of the Directive is the *sui generis* rights. This regime is a particularity of the European Community law. It has not been adopted at a world-wide level, even if such protection is being discussed before the WIPO [65].

2. Databases' content

The nature of the items that compose the content of a database can be very diverse. These items may be of two kinds: material items (such as rocks, stamps, human tissues, etc.) or immaterial items (such as any kind of data, contact details, genetic data, medical data, etc.).

The protection of these items by copyright [66] (songs, photographs, etc.), by other intellectual property rights (patented inventions, trademarks, protected designs or models, etc.) or by other types of rights (privacy as regards medical or genetic data

63 Art. 5 of the WIPO Copyright Treaty adopted on 20 December 1996.

64 Recital 17 and article 1, 2) of the Database Directive.

65 The WIPO's Standing Committee on Copyright and Related Rights has highlighted the necessity of this regime as regards the databases for which the criterion of "originality" was not fulfilled but for which a substantial investment has been made. No firm consensus has been reached yet. See "Legal protection of databases. Submitted by the European Community and its Member States", WIPO Standing Committee on Copyright and Related Rights, Eighth Session, Geneva 4-8 November 2002.

66 This copyright to the content is different from the databases copyright to the database's skeleton. See recitals 26 and 27 of the Database Directive.

for example), may have tremendous influence on the exploitation of the database. Indeed, the creation and/or the use of the database may be hindered by the rights pertaining to the individual items, which are not necessarily owned by the *sui generis* rights owner.

By contrast, such items might also not benefit from any protection at all (such as weather data, astrological data, rocks, anonymous data, etc.).

3. Biobanks' definition

The term "biobank" [67] has not been defined at an international level until the Council of Europe adopted in 2006 its Recommendation concerning the research on biological materials of human origin. Its article 17 states that a *population* biobank is *"a collection of biological materials that has the following characteristics: the collection has a population basis; it is established, or has been converted, to supply biological materials or data derived from it for multiple future research projects; it contains biological materials and associated personal data, which may include or be linked to genealogical, medical and lifestyle data and which may be regularly updated; and it receives and supplies materials in an organised manner"* [68].

Two years before, in its Opinion regarding biobanks for research purposes, the German National Ethics Council had already defined them as *"collections of samples of human bodily substances that are or can be associated with personal data and information on their donors"* [69].

The Organisation for Economic Co-operation and Development (OECD) has referred to biobanks as human genetic research databases [70] and has included the following definition: *"any collection of samples from which genetic samples can be derived and related data (ex. genealogical, clinical, etc.) organised in a systematic way and used for purposes of research"* [71].

67 Some authors have confirmed that biobanks are also known as "genetic databases" or "population databases". B.S. Elger and A.L. Caplan, "Consent and anonymization in research involving biobanks", *EMBO Reports*, Vol. 7, n° 7, 2006, p. 662.

68 Recommendation Rec. (2006)4 of the Committee of Ministers to member states on research on biological materials of human origin adopted on 15 March 2006.

69 Opinion regarding biobanks for research published by the German National Ethics Council in 2004.

70 Organisation for Economic Co-operation and Development, *Creation and Governance of Human Genetic Research Databases*, OECD publishing 2006, p. 35.

71 Cl. Sallée, "Existing Human Genetic Research Databases: Context (Consent Mechanisms and Communication Strategies)". Background paper for the Workshop "Human Genetic Research Databases: Issues of Privacy and Security" held on 26 and 27 February 2004 in Tokyo, Japan.

The UNESCO's International Declaration on Human Genetic Data [72] has embraced the trend which defends that biobanks are composed of biological samples as well as the information derived there from [73].

As we can see from these definitions, biobanks can be composed of a broad range of data. These data may be biological or not, concern the donor or his relatives, or result from the donor's body or from his samples. To us, biobanks may even be constitued with copies made of the donor's DNA (cDNA) that would serve for purposes of experimentation and research, as well as the inventions deriving from such research which may be protected by patent rights.

4. Biobanks' content

Biobanks contain, on the one hand, resource data (also raw data) and, on the other hand, resulting data. The resource data [74] are the biological samples and data, which are donated directly by donors, or obtained indirectly from third parties such as hospitals, laboratories or research centres. The resulting data [75] are the ones which derive from the research experiences carried out with the resource materials.

The resource data are biological samples [76] and information (data) [77] pertaining to the donor. While we could wonder whether or not biological samples do qualify as personal data [78], the information concerning the donor might benefit from data protection law.

As regards the information, it is necessary to distinguish between non-anonymised and anonymised data. The anonymisation of data will largely depend on the purposes sought by the concrete biobank. For instance, some biobanks which attempt to examine and treat patients' illnesses will not anonymise their data until the results have been delivered to donors [79]. By contrast, the so-called "populational genetic

72 International Declaration on Human Genetic Data adopted by the UNESCO on 16 October 2003.

73 A. Cambon-Thomsen, Cl. Sallée, E. Rial-Sebbag and B.M. Knoppers, "Populational genetic databases: is a specific ethical and legal framework necessary?", [2005] 3:1 *GenEdit*, p. 1.

74 We limit the term "resource data" to those originated from donors. There are other types of resource data: computer programs, machines, techniques, etc. which are also very useful in/for biobanks.

75 The resulting data may be considered as resource data by third parties who have not been involved in their obtaining and seek to use them afterwards.

76 "Any sample of biological material (e.g. blood, skin and bone cells or blood plasma) in which nucleic acids are present and which contains the characteristic genetic make-up of an individual", article 2,iv) of the UNESCO's International Declaration on Human Genetic Data.

77 Information can be medical data, human genetic data, human proteomic data, life style data, genealogical data, etc.

78 L.A. Lehtonen, "Genetic Information and the Data Protection Directive of the European Union", p. 111 in *The Data Protection Directive and Medical Research Across Europe*, Data Protection and Medical Research in Europe: PRIVIREAL, Ed. Ashgate, 2004, 253 p.

79 This is often the case of biobanks set up with the aim of making research in the field of pharmacogenomics.

databases" which serve as research infrastructures involving data from different generations within a population or community [80] may anonymise the donors' data from the very beginning of their importation into the biobank.

5. Intermediary conclusion

Comparing the above-mentioned definitions of both terms "database" and "biobank", we conclude that biobanks are indeed databases. They are collections of data and material which are arranged following certain criteria. The data and material contained therein are individually accessible, in a way that a specific information and/or material may be extracted from it. Their elements will generally be independent.

However, depending on the type of material contained in biobanks, the independency requirement will be harder or easier to achieve. For instance, DNA sequences databases might difficultly satisfy the independency requirement. According to some commentator [81], the reason is that on the one hand, the meaning of the functioning of many partial sequences is still unknown and, on the other hand, some of them might have several meanings. This author stresses that when the DNA sequences are partial and their meaning (functioning) is unknown, they might be then considered independent. However as the genomes have been described as the "books of life", it is hard to systematically conclude that their genes might be independent one from the other. Therefore, the criterion of independency might be a source of debates as regards DNA sequences databases.

Biobanks, in their organisational and management aspects, are generally fit up with technical tools (electronic compilation of the data) to allow the systematic and individual selection of their content.

Nor the nature of a biobank's content nor the purposes of its establishment are criterion that could rule them out from the general definition of "database". Similarly, the electronic or non-electronic nature of the devices giving access to a biobank does not play any role when assessing its qualification as database.

We will finally notice that some authors [82] have already remarked that both terms "databank" and "biobank" were indistinctly used in the field.

80 A. CAMBON-THOMSEN, CL. SALLÉE, E. RIAL-SEBBAG and B.M. KNOPPERS, *op. cit.*, p. 2.

81 J.A. BOVENBERG, "Should Genomics Companies set up Database in Europe? The E.U. Database Protection Directive Revisited", [2001] 8 *E.I.P.R.*, p. 364.

82 A. CAMBON-THOMSEN, CL. SALLÉE, E. RIAL-SEBBAG and B.M. KNOPPERS, *op. cit.*, p. 1.

B. *Sui generis* rights on biobanks

As biobanks qualify as databases, they might be protected by *sui generis* rights under certain conditions (1). The *sui generis* rights protect the whole of the database's content or its substantial parts [83] (2).

1. Conditions of protection

(a) *Substantial investment* [84]

In order to benefit from the *sui generis* rights, the database's maker must prove having made some substantial investment therein [85]. The condition of substantial investment is the *ratio* of the *sui generis* rights: such rights are indeed created in order to protect the investments in the obtaining, verification or presentation of the database's content [86].

The substantial investment must be assessed in quantitative and/or qualitative terms. These criteria are not specified any further in the Database Directive. The European Court of Justice [87] (ECJ) has confirmed that the quantitative assessment refers to quantifiable resources while the qualitative assessment refers to efforts which cannot be quantified such as intellectual efforts or energy according to recitals 7, 39 and 40 of the Database Directive. As pointed out by some commentators, on the basis of some EU Member States' national case law, the quantitative substantial investment will not be hard to prove in practice when large sums of money have been invested to build the database [88].

Such substantial investments might be of financial, as well as of human and/or of material nature [89]. Whereas the first type of investment is rather obvious, the investment of human nature includes the expending of time, effort and energy. For instance, the fact of dedicating a researchers' team in order to build up a biobank

83 B. MICHAUX, *Droit des bases de données*, Kluwer 2005, p. 104-105.

84 Literature on this topic: E. DERCLAYE, "Database Sui Generis Right: What is a Substantial Investment? A Tentative Definition", *IIC*, Vol. 36, 1/2005, p. 2-30. See also G. WESTKAMP, "Protecting Databases Under US and European Law - Methodical Approaches to the Protection of Investments Between Unfair Competition and Intellectual Property Concepts", *IIC*, Vol. 34, 7/2003, p. 772-803. M. LEISTNER, "The Legal Protection of Telephone Directories Relating to the New Database Maker's Right", *IIC*, Vol. 31, 7-8/2000, p. 950-967.

85 Art. 7 of the Database Directive.

86 Recital 40 of the Database Directive.

87 ECJ, 9 November 2004, *Fixtures Marketing Ltd v. Oy Veikkaus Ab*, 46/02, ECR 2004, p. I- 10365, at. 38. ECJ, 9 November 2004, *Fixtures Marketing Ltd v. Svenska Spel AB*, 338/02, ECR 2004, p. I- 10497, at. 28. ECJ, 9 November 2004, *Fixtures Marketing Ltd v. Organismos prognostikon agonon podosfairou AE (OPAP)*, 444/02, ECR 2004, p. I-10549, at. 44.

88 E. DERCLAYE, *op. cit.*, 2005, p. 12.

89 Recitals 7, 39 and 40 of the Database Directive.

would be a human investment. The material investment will cover any kind of equipment used to create such biobank [90].

Article 7 of the Database Directive further specifies that the investment must be made in either the obtaining, verification or presentation of the contents. The obtaining is the gathering of the data. The verification refers to the checking, the correction or the update of the data. The presentation involves the retrieval and the communication of the collected data, such as the digitisation of files, the creation of the thesaurus and/or the design of the database layout [91].

According to the ECJ [92], the substantiality must indeed be checked on the basis of the investments (financial, human and/or material) that were only made in such activities. Therefore, quantity and/or quality of data as such should not be taken into account. As some commentators [93] have suggested, should such other assessment influence the granting of the protection, this would lead to the appropriation of the content by virtue of the *sui generis* rights whereas this is not the aim of the Database Directive [94].

Given the efforts and great amounts of money invested in order to set up and maintain biobanks, it is difficult to imagine that creating such databases would not entail any substantial investment in the obtaining, verification and/or presentation of the data. However, the hereunder explained spin-off doctrine could influence such assessment.

(b) *Obtaining/creation of data and the spin-off doctrine*

The substantial investment does not have to be deployed concurrently in the three activities of obtaining, verification or presentation of data. As soon as some substantial investment has been made for one of them, the biobank will enjoy *sui generis* rights. However, two aspects deserve to be highlighted due to their importance for databases, and especially for biobanks.

90 Advocate General Stix-Hackl confirms that the burden of proof of the investment made is on the party who invokes the *sui generis* right. Opinion in the case *Fixtures Marketing Ltd v. Svenska Spel AB* delivered on 8 June 2004, at. 46. Subsequently, the biobank maker will have to provide himself with all the evidences that prove he has made a substantial investment in such activities. See A. STROWEL and E. DERCLAYE, *Droit d'auteur et numérique: logiciels, bases de données, multimédia. Droit belge, européen et comparé*, Bruylant Bruxelles 2001, p. 315.

91 The reference to this last activity may make one wonder whether there is not a certain coincidence with the criteria to be applied for assessing the copyright protection of databases. See P.B. HUGENHOLTZ, "Program Schedules, Event Data and Telephone Subscriber Listings under the Database Directive. The 'Spin-Off' Doctrine in the Netherlands and elsewhere in Europe", Paper presented at Fordham University School of Law, Eleventh Annual Conference on International IP Law & Policy, New York 14-25 April 2003. Available on http://www.ivir.nl.

92 ECJ, 9 November 2004, *The British Horseracing Board Ltd and Others v. William Hill Organization Ltd*, 203/02, ECR 2004, p. I-10415, at. 36.

93 M.J. DAVISON and P.B. HUGENHOLTZ, "Football Fixtures, Horseraces and Spin-offs: The ECJ Domesticates the Database Right", [2005] 3 *E.I.P.R.*, p. 116.

94 Recitals 45 and 46 of the Database Directive.

(i) Obtaining and not creation of data

In the light of the Database Directive [95] and of the ECJ's case law [96], we have to distinguish between the obtaining of data and the creation of data. As already explained, the obtaining of data refers to the acquiring and the gathering of the data. The ECJ [97] refers precisely to the act of seeking out existing independent materials and collecting them in the database. "Creation" refers rather to the production of materials which are part of a database's content.

In order to assess whether a substantive investment has been vested in the obtaining of the compiled data, one must not take into consideration the investment made in order to create these data [98].

The reason of such distinction follows from the subject matter and the *rationale* of the *sui generis* rights: they are meant to protect the investments vested in the creation of the databases, not of the compiled data as such [99]. Therefore, the content of a database is supposed to already exist, so that it can be collected with the purpose of building such compilation.

In some cases, there could not be clear-cut boundaries between the creation and the obtaining stages. In such circumstances, a commentator would advise to consider such mixed activity as an act of obtaining [100].

If we apply this reasoning to biobanks, we would be inclined to conclude that the collection of samples and data from donors (or their practitioners) would fall within the activity of obtaining data, while the data deriving there from as well as the copies of the DNA sequences (e.g. data from which an invention could follow) would rather be considered as creation of data. Indeed, the extraction of DNA sequencing

95 Recital 39 of the Database Directive.

96 ECJ's case law, *op. cit.*, C-46/02, C-338/02, C-444/02 and C-203/02. See also literature on this case law: M.J. DAVISON and P.B. HUGENHOLTZ, *op. cit.*, p. 113-118; T. APLIN, "The EU Database Right: Recent Developments", [2005] 1 *I.P.Q.*, p. 52-68; M. VIVANT, "L'investissement, rien que l'investissement. À propos des arrêts de la Cour de justice du 9 novembre 2004", [mars 2005] 3 *Revue Lamy Droit de l'Inmatériel*, p. 41-48; F. DUBUISSON, "L'interprétation du droit *sui generis* sur les bases de données par la Cour de justice des Communautés européennes: à propos des arrêts *British Horseracing Board* et *Fixtures Marketing* du 9 novembre 2004", [septembre 2005] 7 *R.D.C.- T.B.H.*, p. 734-745.

97 ECJ, 9 November 2004, *The British Horseracing Board Ltd and Others v. William Hill Organization Ltd*, 203/02, ECR 2004, p. I-10415, at. 31.

98 The same principles apply to the verification and the presentation of data: the resources used for the verification and the presentation of materials during the stage of their creation and which are subsequently collected in a database do not fall within that definition.

99 ECJ, 9 November 2004, *The British Horseracing Board Ltd and Others v. William Hill Organization Ltd*, 203/02, ECR 2004, p. I-10415, at. 30.

100 Advocate General Stix-Hackl has stated that there would be "obtaining" of data if the creation of data took place at the same time as its processing and was inseparable from it. Opinion in the case *Fixtures Marketing Ltd v. Svenska Spel AB* delivered on 8 June 2004, at. 59. See also A. MASSON, "Creation of Database or Creation of Data: Crucial Choices in the Matter of Database Protection", [2006] 5 *E.I.P.R.*, p. 264.

from biological tissue, for instance, comes at an ulterior moment, namely after the obtaining of such tissue has taken place. Such activities repartition is however far from being clear-cut. Indeed, some commentators [101] have argued that it is difficult to determine whether the genetic sequences have been created or collected by scientists. On the one hand, these data pre-exist already in nature, they can therefore be recorded by anybody. On the other hand, they can be qualified as created data *"as they did not exist before in any intelligible form"*. It is however not sure whether such criterion is to be applied in order to draw a line between creation and obtaining.

Such considerations are especially relevant for biobanks, as the resource materials and the resulting materials are often combined: in such situation, one must stress that the ECJ requests database makers to prove the independency between the substantial investments made in the creation of data and those put in the obtaining, verification or presentation of data [102].

This important precision being brought, its influence is likely to be lessened in practice. Biobanks are indeed likely to benefit from *sui generis* protection, no matter whether or not the data gathered therein have been obtained or created, for the normal setting up, feeding and maintenance of a biobank shall generally imply substantial investments vested in its verification and/or presentation.

(ii) Spin-off doctrine

The substantial investment has to be made in the creation of the biobank as such. The collection, verification or presentation of data must therefore not have been performed in the framework of a primary activity (e.g. patients' medical examination) which is not linked to the setting up of the biobank [103]. Such substantial investment made in such prior activity should not be taken into account when assessing the substantial investment criteria in a claim for *sui generis* protection. For example, the investment that would have already been made in the taking of the samples or data for diagnosis purposes should not be counted within the investments made for the setting up of the biobank. On the contrary, if the taking of such material or data was done specifically with the aim of setting up the biobank, such investments would then have to be taken into account.

Generally, the independency between the setting up of a biobank and other activities such as diagnosing patients should normally not be difficult to prove, as the two activities seem, at the end of the day, quite distinctive. One could however imagine medical

101 E. Derclaye, "Databases "Sui Generis" Right: Should we Adopt the Spin-off Theory?", [2004] 9 *E.I.P.R.*, p. 411.

102 ECJ, 9 November 2004, *The British Horseracing Board Ltd and Others v. William Hill Organization Ltd*, 203/02, ECR 2004, p. I-10415, at. 35.

103 It is the so-called spin-off doctrine. See P.B. Hugenholtz, *op. cit.*, 2003. Also E. Derclaye, *op. cit.*, 2004, p. 402-413.

fields wherein creating or obtaining the data and the constitution of biobanks therewith is part of the care provided to the patient, such as pharmacogenomics, for example.

2. Extent of the *sui generis* protection

(a) *Principles*

The protection of biobanks by *sui generis* rights grants to their maker(s) [104] exclusive rights on acts pertaining to the *extraction* [105] and *reutilisation* [106] of the biobank's data. The biobank maker has thus the power to authorise or forbid third parties to perform these acts provided they are performed on the whole or on a substantial part of the biobank [107].

The substantial character of any extraction or reutilisation has to be measured in quantitative and/or qualitative terms. In order to proceed with such assessment, the ECJ seems to compare the investment vested in the considered extracted or reutilised part of the database with the investment made in the obtaining, verification and/or presentation of the whole of its content [108].

104 The maker of a biobank, as of any other compilation of information and material, is according to recital 41 of the Database Directive "the person who takes the initiative and the risk of investing". The subcontractors are excluded from the qualification of database maker. In the case of biobanks, the maker will usually be a legal person (e.g. State, foundation, private company, etc.).

105 Art. 7, 2 (a) of the Database Directive defines "extraction" as the "permanent or temporary transfer of all or a substantial part of the contents of a database to another medium by any means or in any form". This includes copying (either temporary or not), downloading, uploading, modifying, translating, adapting, etc. the biobank's content on any other medium than the original one.

106 Art. 7, 2 (b) of the Database Directive defines the "reutilisation" as "any form of making available to the public all or a substantial part of the contents of a database by the distribution of copies, by renting, by on-line or other forms of transmission". The reutilisation comprises the uploading of a biobank's content on the Internet, its public display, and its distribution on CD-Rom or DVD for example.

107 See ECJ, 9 November 2004, *The British Horseracing Board Ltd and Others v. William Hill Organization Ltd*, 203/02, ECR 2004, p. I-10415, at. 50.

108 ECJ, 9 November 2004, *The British Horseracing Board Ltd and Others v. William Hill Organization Ltd*, 203/02, ECR 2004, p. I-10415, at. 70 and 71. The ECJ has stated that *"the 'substantial part, evaluated quantitatively', of the contents of a database within the meaning of Article 7(1) of the directive refers to the volume of data extracted from the database and/or reutilised, and must be assessed in relation to the volume of the contents of the whole of that database. If a user extracts and/or reutilises a quantitatively significant part of the contents of a database whose creation required the deployment of substantial resources, the investment in the extracted or reutilised part is, proportionately, equally substantial."* As regards the 'substantial part, evaluated qualitatively' of the contents of a database, it has confirmed that it *"refers to the scale of the investment in the obtaining, verification or presentation of the contents of the subject of the act of extraction and/or reutilisation, regardless of whether that subject represents a quantitatively substantial part of the general contents of the protected database. A quantitatively negligible part of the contents of a database may in fact represent, in terms of obtaining, verification or presentation, significant human, technical or financial investment"*. The ECJ has further confirmed in its at. 76 that *"In order to assess whether those materials represent a substantial part, evaluated qualitatively, of the contents of the BHB database, it must be considered whether the human, technical and financial efforts put in by the maker of the database in obtaining, verifying and presenting those data constitute a substantial investment."* M.J. Davison and P.B. Hugenholtz, *op. cit.*, p. 116.

The control exercised by the biobank maker on the exploitation of his biobank extends also to the extraction or reutilisation of non-substantial parts of the content which are carried out in a repeated and systematic way on condition that it implies a conflict with the normal exploitation of the database or that it unreasonably prejudices the database maker's legitimate interests [109].

(b) *Substantial extractions of biological samples: the depletion of the biobank?*

Sui generis rights aim to protect any database, regardless of the nature of its data, against some extractions and reutilisations of its content. The right of extraction involves the transfer of the content from the original database to any other type of support. Normally, this concept is very similar to the notion of reproduction in copyright (see *supra*) [110]. Indeed, one of the main objectives of the lawmaker was to protect computerised databases against total reproductions or parasitic and automatic extractions for reuse in competitors' databases. Therefore, the protected extractions were normally not thought to lead to the removal of the database's content.

For instance, with regard to biobanks, the donors' electronic data can easily be copied and their extraction may therefore occur without removing them from the database [111].

However, their biological samples may be subject to another phenomenon. Indeed, the extractions of biological samples from the biobank are of physical nature. In frequent cases (involving uncultivable or irreproducible materials), such physical extraction could lead to a progressive depletion of the biobank's content, and to the subsequent necessity to collect more samples from donors [112]. In other words, each extraction would affect and reduce the content of the biobank, and would imply further investments in order to replace the extracted items.

According to us, such depletion effect would influence the assessment of the substantiality of the extraction in qualitative as well as quantitative terms. From a qualitative point of view, we would intent to think that, as some samples cannot be reproduced, or at least would involve special investments in order to be reproduced

109 Art. 7, 5) of the Database Directive. Note that whether the purpose of the extraction and/or the reutilisation is the creation or not of another database is irrelevant in order to assess infringements to *sui generis* rights. See ECJ, 9 November 2004, *The British Horseracing Board Ltd and Others v. William Hill Organization Ltd*, 203/02, ECR 2004, p. I-10415, at. 47.

110 B. MICHAUX, *op. cit.*, p. 152.

111 The extractions of scanned mammograms from a biobank will not deplete the latter. The mammograms will remain available to the researchers within the biobank.

112 Biobanks makers keep confidentially and preciously the donors' information to ask their additional consent for a new taking of their samples. This practice extends also to the collecting of information.

or replaced, the extraction of the latter is more likely to be substantial than the extraction of easily reproducible data. From a quantitative point of view, the substantiality of the amount of demanded samples vis-à-vis the biobank's content would vary according to the depletion status of the biobank.

C. Conflicts with privacy rights and third parties' interests

Biobank makers can, to a certain extent, control the access and the reuse of the data contained in their biobanks. Such exploitation may have critical consequences with regard to donors and third practitioners. Indeed, the personal relationship between the donor and his data needs to be taken into account [sections 1 and 2].

From the third practitioners' perspective, biobanks represent a vital tool to perform their researches. The access and use of these tools become crucial for research centres, hospitals and laboratories which do not dispose of the costly equipment and resources to start up and maintain such collections of materials [section 3].

A balance needs therefore to be established between the interests in presence.

1. Role of the donor

The donor is not without any important role in the setting up of a biobank. Donors' samples and data are the bricks the biobank is made with. Furthermore, even when a biobank is operational, the maintenance and update of its data is vital: the donors' samples and data renewal will be one of the key elements to perpetuate a biobank's development.

Such collection of donors' samples and data is subject to the application of personal data protection rules [113].

Biobank makers will not have to comply with any obligation from the privacy point of view provided that those data are anonymised. Anonymisation is a key feature as regards most types of biobanks: once data are anonymous, the privacy rights of their donors are disabled [114], and the exploitation of the biobank is therefore not hindered by such rights.

In the cases where the data would not be anonymised, the privacy laws fully apply. Questions concerning the reutilisation of the donors' samples [115] and data, as well as

113 See other contributions to this book.

114 See recital 26 of the Data Protection Directive.

115 Art. 22 of the Oviedo Convention insists on the necessity of adopting appropriate information and consent procedures when a removed part of the human body is stored and used for other purposes than those of its removal. Council of Europe's Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, adopted in Oviedo 4 April 1997 and its Protocols.

the compatibility between the purpose (e.g. diagnosis) of the first processing and the purpose of the reutilisation will arise. If such reutilisation seeks the performance of scientific purposes [116], then it may be grounded on public interest(s) [117]. If both processing are compatible, the donors' consent to the second processing does not seem to be mandatory provided some conditions are satisfied [118]. But he may however always exercise his right to oppose to such processing [119].

2. Data protection rules and *sui generis* rights: primacy or cohabitation?

The relationship between the data protection rules and the database rights is scarcely enlightened by a specific recital included in the Database Directive, which reads: "[...] whereas the provisions of this Directive are without prejudice to data protection legislation" [120]. The same recital insists also on the divergent aims of both the Database Directive and the Data Protection Directive. According to the European lawmaker, the provisions of the Data Protection Directive remain fully applicable despite a potential protection of the data by database rights.

In its recital 41, the Data Protection Directive gives also some guidelines as to the relationship between privacy rights and intellectual property rights: "[...] Whereas this right [the access right of the data subject] must not adversely affect trade secrets or intellectual property and in particular the copyright protecting the software; whereas these considerations must not, however, result in the data subject being refused all information". From the reading of this recital, one remarks that even if the data subject always benefits from his data protection rights, these rights should not be exercised beyond their purposes, in a way that would damage or jeopardise the intellectual property of others.

The relationship between donors' data protection rights and the biobank maker's *sui generis* rights presents the features of cohabitation, most of all given that their scope of protection differs. The data protection rights aim at protecting the data subjects

116 The scientific purpose "consists in establishing permanent principles, laws of behaviour or patterns of causality which transcend all the individuals to whom they apply". Recommendation n° R (97) 18 of the Committee of Ministers to Member States concerning the protection of personal data collected and processed for statistical purposes. Adopted by the Committee of Ministers on 30th September 1997 at the 602nd meeting of the Ministers' Deputies.

117 Art. 8, 4) of the Data Protection Directive.

118 For an international overview of the consent procedure in the reutilisation of samples and data, B.M. KNOPPERS, "Biobanking: International Norms", Symposium Regulation of Biobanks, Spring 2005, *Journal of Law, Medicine & Ethics*, p. 7-14.

119 L. DEPLANQUE and M.-N. VERHAEGEN, "La réutilisation des données à caractère personnel relatives à la santé en recherche médicale sous l'angle du droit belge. Quand l'intérêt de la recherche rencontre celui de la protection de la vie privée du participant", *T. Gez/Rev. Dr. Santé*, 2004-2005, p. 25-26.

120 Recital 48 of the Database Directive.

(from the harm that may be caused by an adverse use of their data), while the *sui generis* rights do not intend to protect the data as such but rather the investments made in the collection, the verification or the presentation of the data as a whole.

Should a donor want to consult his health data contained in a biobank, such request could only create tensions if it involves extraction of substantial parts of the biobank. Indeed, if such extraction is protected by *sui generis* rights, then the question arises whether these rights may be overridden by the donor's access rights. As stressed by the Data Protection Directive, intellectual property considerations may not result in the data subject being refused all information. The data subject's access right should therefore prevail, as long as this request pertains strictly to his personal data and is issued for medical or other personal purposes. Such limitation to database owner's extraction right should never be considered as a general licence to the database or the considered substantial part. Indeed, this limitation being grounded on data protection rights and/or health law principles, the use of the data should be limited to the rights and interests protected by these legislations. In other words, once the data subject has accessed his personal data (by extracting a substantial part in the database), he would still need the authorisation of the database's owner to 'sell' these data to a commercial databases' maker for example.

Such limitation to the database's owner rights could cover both the extraction and reutilisation of the data. The access granted to the data subject will generally lead to an extraction according to the definition of the Database Directive. Furthermore, a patient could transmit the extracted health data to a practitioner, on basis of his right to self determination [121].

3. The real influence of database rights on biobanks?

Intellectual property and the exclusive and monopolistic rights they entail, are often questioned when they seem to hinder scientific research and public interest. Such debate may also arise as regards biobanks and their protection by *sui generis* rights.

On the one side, researchers need to access to biobanks in order to extract and use their content to perform their researches. On the other side, biobank makers control such access and may further own database rights thereon.

Access to biobanks is prior to any possible use of the latter. Access as such is however not part of the *sui generis* rights' scope of protection [122]. The "access right" exercised by the biobank maker is rather based on material property law [123] and service contractual clauses, but not on intellectual property as such.

121 *Cf. supra.*

122 One must note however that the access to computerised database generally involves temporary transfers or reproductions that are covered by the definition of "extraction".

Such access will be granted or not according to the policies of access adopted by the biobank maker, if any. The common practice is the signature of agreements between the biobank maker and the researcher(s). The terms and conditions of such agreement may vary from one biobank to another. The granting of access to researchers will depend, among others, on the purposes of the research, and even sometimes on the research outcomes that biobank makers may get in exchange.

Some public biobanks for example require from researchers not to pass on the resource materials to any other researcher, but to share the results of their research [124]. In exchange, researchers may order and receive (usually by post) samples of the biological content or non-electronic data which cannot be accessed directly by researchers. With regard to the electronic data, the access may be organised by way of membership schemes, and/or controlled by classical user's name and password systems. This is normally done in exchange of a fee [125]. Some biobank makers may also adopt an open access model.

When researchers have had access to the samples or other data, the subsequent operations they are allowed to carry out with these materials may differ according to the type of agreement concluded with biobank makers. Even if the latter do not claim their *sui generis* rights in such contractual clauses [126], they may decide to enforce these rights and thus control the extraction and the reutilisation of such data. Biobank makers remain indeed entitled to restrain such activities in case substantial part of the biobank's content should be the object of these acts.

Indeed, the scope of the *sui generis* rights may sometimes extend to some further acts performed by the researcher with such data. For instance, the copies of such data, their insertion in another biobank, or anywhere else, their communication to third parties by any mean, could fall within the *sui generis* rights, should such acts qualify as substantial extractions and/or reutilisations as described above. In such cases, researchers have to respect these rights and, accordingly, ask the biobank maker's prior consent before carrying out any of those acts, unless some limitations to *sui generis* rights apply. For example, if the purpose of the extraction is the illustration for scientific research, the researcher will generally not need to ask such consent on

123 We do not refer to the property of biological samples as such, which is a concept that may be questioned, but rather to the property of the facilities and infrastructures wherein they are kept.

124 This practice is much extended in the domain of natural sciences. In this sense, read S. BRANDT-RAUF, "The Role, Value, and Limits of S&T Data and Information in the Public Domain for Biomedical Research", *The Role of Scientific and Technical Data and Information in the Public Domain*, Proceedings of a Symposium, The National Academies Press, Washington D.C., 2003, p. 69.

125 This fee helps in the funding of biobanks, even the public ones which generally do not dispose of long-term investments.

126 Many biobanks have not even yet adopted a policy on intellectual property rights.

condition that he indicates the source of the information and that the extent of the extraction is justified by its non-commercial aim [127]. When the conditions of the limitation are fulfilled, the researchers may carry out the reproduction, the modification, etc. of a substantial part of the biobank, but not its reutilisation (as defined in the Database Directive).

In order to assess the impact of the database *sui generis* protection on the exploitation and management of biobanks, one must never forget the dual nature of biobanks: electronic databases coupled with material samples that are kept in specific facilities. While *sui generis* rights may not usually play a major role in the exploitation of material samples and the non-electronic data, their protection as to the digitised data may prove to be very influential, as such part of the biobank may be easily copied and reused. However, even if biobank makers can control each extraction of physical samples, one could imagine situations where they could call upon their *sui generis* rights, should they realise, for example, that someone is systematically ordering samples (DNA fragments, for example) in order to build up and exploit a new biobank on the side.

We can therefore conclude that researchers are led to deal with different types of legal regimes according to the way they get access to the biobank, the type of materials they want to use, the type of researches they aim to carry out, the biobank makers' policies, the contracts they sign, and indeed finally, the will of the biobank makers to enforce or not their *sui generis* rights.

These factors shall generally differ depending on the exploitation model that is upheld. The application of one model or another will generally vary according to the nature and the source of the data, the funding behind the biobank, its *rationale*, etc.

We however have to highlight that, in any case, from the researchers' point of view, the crucial stake as regards biobanks seems to remain their conditions of access. Database *sui generis* rights may only have some influence on the way the database and its content are used, once such access has been granted.

4. Intermediary conclusion

Biobank makers will generally be vested with *sui generis* rights in their biobanks' content. The third parties' interests at stake with regard to the exploitation of biobanks may be, on the one hand, the donors', and on the other hand, the researchers'.

As far as donors' interests are concerned, some biobanks' content is anonymised, which will usually disable privacy data protection. The anonymisation of the

127 Art. 9, b) of the Database Directive.

donors' data entails that the latter cannot claim any rights thereon: there should therefore not be any conflict between their interests and those of the biobank maker. Sometimes, the introducing of a patient's data and samples into a biobank may be inherent to his treatment and the prescription of his medicines (in pharmacogenomics, for example). In such case, privacy law will fully apply, and will certainly greatly influence the exploitation of the database.

The main problem that researchers face as regards biobanks is their access. Once such access is obtained, other hindrances may be of contractual nature. Eventually, *sui generis* rights may intervene depending on the way the biobank and its content is used.

General conclusion

The important principle we wanted to highlight and illustrate in this contribution is that medical data, as any other kind of sheer information, may normally not be appropriated or monopolised by way of intellectual property.

Copyrights protect the form of the work, as long as it is original, and not the data that it embodies: anyone may therefore always extract and reuse data embedded in a copyrighted work.

Contrary to copyright, which protects the structure of a database as well, *sui generis* rights are presented as protecting the content of the latter. However, such *sui generis* rights do only regulate the "extraction and/or reutilisation of substantial parts" or the "repeated and systematic extraction and/or reutilisation of insubstantial parts" of the content of the database: one must therefore stress that this protection does not either entail any rights on the data or information as such, but only as being part of a specific ensemble, and only as far as it is proved that such ensemble has actually been extracted from the protected database and/or reutilised.

One could however retort that, sometimes, copyright or *sui generis* rights protection equals to indirectly protect the embedded data. As regards copyrights, it is possible to imagine some cases where it would seem difficult to extract the information from a protected work without reproducing protected parts of it. This is especially the case with visual materials. Indeed, it would seem difficult to accurately extract all pertinent medical information from a mammography for example, without actually making a complete reproduction of the picture. The sole possible alternative would be to redo a new shot, but even in that case, this would imply that the status of the patient would not have evolved, which will sometimes not be the case. In some situations, one X-ray shot will therefore be the sole exemplary of the patient's medical status at a precise time, and the only way of transfering these data will be to reproduce the work.

Similar situations may occur as regards databases. Biobanks will usually be unique, not only because of the tremendous investments they represent, but also for their content may not realistically be found anywhere else (because of the rareness of the specimens or samples gathered in these biobanks for example) [128].

Intellectual property could affect the accessibility and the reuse of medical data, not because they create a monopoly on such data, but because they may protect their unique source, and therefore somehow affect the extraction and/or reutilisation of such data.

As analysed in this contribution, such intellectual property rights should step aside for the patients' fundamental rights in case of conflicts. The patient should indeed always be granted the right to access and reuse his data for medical or private purposes, conforming to the principles established by the data protection legislations and by medical law and ethics.

When it comes to medical researches, the main issue appears to be the researchers' access to data. As hereabove set forth, the owners of databases usually have the total physical and/or electronic control on this access, and can further regulate it by the way of contractual clauses. Such contractual provisions may condition not only the access but, in many cases, the use of the database as well. Database rights might only play a secondary role at a sub-layer level, and this only if such use enters into the scope of this specific legislation.

[128] Such situation is not without somehow reminding the European case-law dealing, from competition law prospective, with copyrighted information sources or *de facto* standards, and which finally reached to judicial compulsory licensing. ECJ, 29 April 2004, *IMS Health GmbH & Co. OHG c. NDC Health GmbH & Co. KG*, 418/01, ECR 2004, p. I-5039. ECJ, 6 April 1995, *Radio Telefis Eireann (RTE) and Independent Television Publications Ltd (ITP) v Commission of the European Communities*, 241/91 and 242/91, ECR 1995, p. I-00743.