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INTELLECTUAL PROPERTY ON MEDICAL DATA CHIMAERAS AND ACTUALITY

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Medical data is usually addressed by lawyers from a privacy point of view. However, intellectual property is increasingly put forward when discussing the control, the use or the transmission of medical data. Even if medical data relates to patients and is moreover protected by very strict data protection and secrecy rules, this information is nonetheless "created", sorted, structured, explained and, more generally, processed by the professional practitioners and medical administrations. Given this processing of the data and the drafting of files and reports concerning the health condition of the patients, one could indeed assume that these intellectual investments should be worth some legal protection. One should however still bear in mind the particularities of the considered data and the strict conditions to be fulfilled in order to benefit from one or another intellectual property right.

This paper may be seen as an introduction to the application of Intellectual Property to medical data, tackled on the basis of two examples. The first part will focus on the application of copyright rules to medical records of patients. The second part will address the protection of biobanks from a database and patent rights point of view.

PART I. Copyright to medical records?

I.1. Ideas and information are free

Is there was to ever be a golden rule in copyright, then this would probably be the one. By utilizing this as a paradigm, several copyright principles emerge that will be summarized hereunder.

Copyright is a free and automatic protection that is granted without any formality on literary and artistic works, which include amongst others, any production in the scientific domain. Copyright is only granted to works that are expressed in a certain form[1] and are original.

The meeting of the first condition, namely the embodiment of the work in a form, is the starting of the protection by copyright: copyright is granted at the moment of the creation of the work. This condition specifies also the subject matter of copyright: copyright protection only extends to the form of the work, and not to the underlying ideas or information. As regards scientific articles, for instance, copyright will never protect the facts, figures, information, theories, discoveries or other scientific analysis 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.

The second and last condition for a work to be copyrighted is originality. The definition of an original work differs slightly from one legal system to another. In civil law countries (such as Belgium or France) this means that the work should be marked by the personality of the author. In Anglo-Saxon countries, this will imply that the work must originate from the author who should have expended "skill, judgement and labour" on its creation. In both systems, this condition entails that the author should at least have a breathing space allowing him to choose the way he will express himself and give 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.

Medical codes of ethics or patient rights regulations usually provide for minimal content of patients' records, such as 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. A medical record that only consists of the gathering 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. The "author", namely the practitioner entitled with copyright, could therefore normally benefit from some exclusive rights on this "work". He would have the exclusive right to authorise or forbid any reproduction of the record and its communication to the public by any mean (including diffusion on the internet), unless one of those acts is covered by an exception to copyright. Furthermore, on the basis of his moral right, the practitioner would have the right to agree or not with the divulgation of the work, to claim for credits and to oppose any modification.

I.2. Copyrights against patients' rights?

A practitioner in a position to claim copyrights on a patient record should be entitled exclusive rights to control the reproduction (including modification, translation, digitalisation, etc.) 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. Those important specificities have a dramatic influence before and after the creation of the "work" and its protection through copyright.

The work is created with data relating to the patient, his body, his health and the treatment he undergoes. This data is subject to very strict sensitive data protection and privacy rules. Furthermore, it is collected in a practitioner – patient relationship, which is governed by professional ethics and secrecy rules. Even before creating the work, the practitioner is bound by those rules and must respect the special nature of the data. Accordingly, the processing of the data may only occur with the agreement of the patient, and conforming to the law, the purposes of the processing and the proportionality principles. Actually, at this

level, the creation of a copyrighted work with the data may be analysed as being part of the processing of the data, namely the creation of a record with the data. Therefore the creation of the work is only possible thanks to the will of the patient to choose this practitioner and to communicate to this latter his personal data. As a preliminary question, one could wonder if this agreement of the patient 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 loyal behaviour towards the patient. At the very least, one could argue that, in such situation, the agreement of the patient is given completely in the framework of a trust relationship and on the implicit condition that the practitioner respects his patient's rights.

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: 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 the copyrighted work. 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, his secrecy obligations and the laws on data protection. In practice, it means that he will almost always need the authorisation of his patient.

Could he however invoke his copyrights towards colleagues, medical institutions or even his client himself? In other words, knowing that the author could have some copyrights on his record, should the client ask the permission of its author in order to reproduce or communicate the work to somebody?

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. Where some costs may be charged to the client for exercising his right to get a copy, these costs would only cover the administrative and/or material disbursements and in no way any "royalty". 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 at the moment), the right to receive a copy of the record derogates 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.

Once in possession of a copy of his record, according to copyright rules and related exceptions, the patient could only make private copies and communicate the work privately (usually, only within the family circle). Accordingly, from a strict copyright prospective, the patient could not communicate his record to anybody outside his close family without the author's consent. In such scheme, one could imagine a practitioner or a health institution could not allow his patient to communicate his record's copy to a competitor in order to restrain their clients from going elsewhere, or could sell the transfer of the record. This idea is quite appalling and such deviant use of copyright could instinctively be deemed abusive and unethical.

This practice would be contrary to some fundamental rights of the patient. 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[2]. During a period of time, the French public health code provided explicitly that the patient was the owner of his record. 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, which is an idea that is, as such, strongly criticised. 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. Whereas it is difficult to accept the existence of a right in *rem* relating to immaterial and abstract subject matter such as information, we do not back up the idea of an intellectual property on patient's 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 determination. This right confirms the autonomy of the patient in the caring for his health, and its corollaries are the free choice of professional practitioner and the liberty to change the latter.

In summary, as well as the author not being able to oppose the patients' right to attain a copy of his record, the author cannot oppose the communication of this record to a competitor, nor the modification and reuse of this 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.

Finally, in the rare cases where a practitioner could claim copyrights on certain elements of his patient's record, one could wonder in which circumstances and towards whom this practitioner could actually enforce these copyrights. At first sight, one could put forward that the copyrights of the practitioner could be enforced in cases whereby 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 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.

Should we have to summarise the analysis that is outlined here above, we could draw a general principle according to which, even if in some special and rare cases, practitioners could possibly be granted copyrights on the records they created, those copyrights should never be used in order to distort the patient's rights.

PART II. Intellectual Property on biobanks?

Biobanks are known as the compilations of human biological material (organs, tissue, cells, blood, DNA, etc.) where each sample usually contains very personal information of the donator[3]. These samples might have been collected through diagnosis and treatment procedures, or else, on the sole purpose of creating a biobank.

These compilations represent, for their creators, great investments, in terms of effort, funding, human resources and time. This is the reason why the creators of biobanks seek the protection of their work, especially through the intellectual property right regime.

However, can those rights protect biobanks? If so, who is the right owner and what are its prerogatives?

II.1 Databases

A database is a collection 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[4]. It may contain a wide range of material items (such as rocks, stamps, human tissues, etc.) or immaterial items (such as any kind of information, contact details, medical data, etc.). One must bear in mind that those items may be protected by copyright (songs, photographs, etc.), by other intellectual property rights (patents, trademarks, etc.) or by other types of legal protection (privacy as regards medical data for example). On the contrary, they also might not benefit from any protection at all (such as weather data, astrological data, rocks, etc.).

Biobanks are to be considered as databases. The fact that they contain biological material doesn't lead to their exclusion from the database regime.

Databases consist of a structure and some content. The structure is the frame, the "container", where elements are arranged following some criteria of selection chosen by the creator. The indexation and the search systems, as well as the whole layout of the database and its interfaces, are also part of this structure. The content represents the sum of all the elements, which are gathered and individually accessible in the database.

This distinction between the structure and the content is very important for the analysis of the protection provided for by intellectual property rights. Databases may be protected by traditional copyright and/or by another specific database right often referred to as "*sui generis*" right. Copyright and *sui generis* rights protect databases differently according to their objects and criteria of protection.

Copyright protects the structure, as long as it is original. In other terms, copyright will extend to the criteria of selection, the indexation and search systems, the layout and the interfaces as long as they are marked by the creator's personality or prove to be the result of the creator's "skill, judgement and labour". In order to appraise the originality of the structure, one will also take into account, colours, forms and schemas employed in the disposition and presentation of the elements within the database. This reasoning is exactly the same as regards biobanks. Indeed, the way the different biological materials are sorted, classified, linked together and accessible, on the basis of indexation menus, descriptions, entries, etc. may be copyrighted.

Depending on the terms of the contracts pertaining to the creation of the structure of the biobank, and their role in that creation either the practitioner, the hospital, any other contractor or any combination of them could be the copyright owner(s). Copyright entitles its owner(s) to prevent any other person from reproducing and communicating the database's structure to the public. However, some third parties will benefit from certain

exceptions in specific circumstances involving public security, teaching and scientific researches purposes, private purposes, or other legitimate interests.

Databases may also be protected by *sui generis* rights. *Sui generis* rights protect the substantial investment of the database's maker from a qualitative and quantitative perspective in either the obtaining, verification or presentation of the content. The obtaining refers to the collection of data or items. The verification pertains to the checking of the accuracy of the data or the items when the database is created and during its operation. The presentation relates to the processing of the data, as well as to their organisation, in order to ensure their individual access and their methodical arrangement. The term "investment" refers not only to money but also to time, effort and human resources invested in those activities.

The *sui generis* rights owner is the person who has made the investment. In the case of biobanks, it might frequently be the hospital or research institution. By virtue of this right, this entity is enabled to prohibit the substantial extraction and reuse of the database by any third party. On the contrary, non-substantial extractions and reuses may be undertaken by third parties, without the right owner's authorisation, as long as these acts aren't made in a repeated and systematic way that would imply a conflict with the normal exploitation of the database or produce an unreasonable prejudice to the legitimate interests of the database's maker[5]. The substantiality is assessed from a quantitative and a qualitative points of view. These criteria are highly variable from one case to another, what implies that judges will play an important role in their application and interpretation.

Accordingly, *sui generis* rights might protect biobanks. This protection is weaker than copyright because only biobanks demanding a substantial investment in the obtaining, the verification or the presentation of their content may be protected and anyway, the non-substantial extraction and reuse can be carried out by anybody without the right holder's permission.

Moreover, a theory restraining the application of the *sui generis* rights protection, and more precisely narrowing the substantial investment condition, has appeared in the late 90's in The Netherlands and is increasingly spreading its influence throughout Europe. According to this so-called *spin-off* theory, the by-products resulting from activities whose main objective aren't the obtaining, verification and/or presentation of the content of the database cannot enjoy *sui generis* rights. The *spin-off* theory is grounded on the necessity of a link between the substantial investment in any of those activities and the aim of creating a database. In other words, any investment made in order to pursue another aim than creating a database should be put aside when assessing the fulfilment of the investment condition to obtain a *sui generis* right. This theory has already been examined by the European Court of Justice which has clearly stated that the fixture lists containing dates, time, etc. of matches of the British football league are considered as databases, but cannot be protected by *sui generis* rights because of the lack of substantial investment. Indeed, the normal activity of the British football leagues, which is basically to organise the dates and times of home and away teams playing in the matches, is so integral to the creation of the database's content, that it cannot claim any *sui generis* rights on it[6]. A similar situation could occur in the medical sector. One can imagine two extreme hypothesis: a) The hospital's staff stores in a biobank, for hypothetical further research purposes, samples resulting from everyday-treatments applied to patients (in this case, we will suppose that no other work is done than

the mere storing of samples that were used in order to treat the patients); and b) The hospital's staff collects samples from patients exclusively in order to create a biobank. If we apply the spin-off theory, the first biobank wouldn't be protected by *sui generis* rights, while the second one would be. In the first case, the hospital hasn't invested in the obtaining, verification or presentation of the samples gathered in the biobank. It has paid its staff, spent time and invested in medical devices in order to care for the patient's health. Subsequently, it has reused the patient's samples in the framework of a biobank with research purposes, without doing any other extra substantial investment. Therefore, there are no *sui generis* rights. This means that, from a strict *sui generis* right point of view, and leaving aside any other concern pertaining to the biobank or its content (such as privacy protection, confidentiality clauses, secrecy rules, access rights, technical means, contractual provisions, etc.), any third party could extract and reuse substantial parts of the biobank's content without the hospital's permission. In the second case, the hospital has expended its funding, resources, effort and time in the three activities above-mentioned, which lead to the creation of a database. For this reason, the hospital would hold *sui generis* rights. It seems logical to proceed this way, especially when we look at the function of the *sui generis* rights, which is the protection of the database maker's substantial investment. If there is no substantial investment, there are no *sui generis* rights on the database to claim against third parties.

We have already mentioned that each item that is inserted in a database might also be legally protected. In the case of biobanks, can biological materials enjoy any protection? First of all, biological materials consist of samples of tissue, DNA, blood, cells, etc. which have been extracted from patients. In order to take those samples from the patients, the practitioner must have asked the patients' consent and explained them the purpose of the analysis or treatment. Once these samples have been obtained, the practitioner or the hospital may decide to gather them in a biobank for research purposes. However, once again, this may only be done with the preliminary and informed consent of the concerned patient. The ulterior commercialisation of this biobank would also be subject to the patients' consent. In other words, one must stress that the items that are gathered in the biobank are first of all protected by data protection and secrecy rules. Could intellectual property rights protect these items? One could not seriously imagine claiming any copyright on human biological materials, unless one could first pretend that these materials may be considered as literary and artistic works, which seems at first sight to be difficult as well as inept. Given the recent developments as regards the patentability of biotechnology, patent rights may also be considered. Indeed, for example, the isolation of the samples in order to be identified, purified, classified and reproduced outside the human body may lead to an invention susceptible of being protected by patent[7]. Therefore, depending on the interventions and treatments applied to the samples, those database items could be patented or patentable.

II.2 Protection by industrial property rights: patents

The use of biobanks, and specially, the researches carried out on the basis of their content might result in an invention, which is, according to the traditional definition, a technical solution found to solve a technical problem. An invention may be the subject of a patent if the conditions of protection are met and if formalities (the filing of applications) are executed by the inventor.

In order to be patentable, an invention must fulfil three conditions, namely novelty, inventive step and industrial application.

An invention is new if it is not part of the state of the art, which comprises everything made available to the public by any mean, before the filing date of the patent application. An invention is inventive if having regard to the state of the art, it is not obvious to a person skilled in the art. The criterion of industrial application refers to the adequacy of the invention to be used in any industrial sector, comprising the agricultural field.
The patent holder can prevent third parties from using, manufacturing, selling, exporting, importing and exploiting its invention, without its authorisation[8]. This right lasts 20 years after the filling of the patent application.

The inventions resulting from researches and developments made on the basis of a biobank could probably be biotechnological inventions. At European level, the protection of these inventions formed the subject of important controversies that resulted in the adoption of directive 98/44/EC[9]. In the framework of this paper relating to intellectual property rights on medical data and to the conflicts that may occur between those rights and the patients' rights, we must draw special attention on the debate surrounding the patient's informed consent to the filing of a patent on a biotechnological invention based on his own biological material. Indeed, recital 26 of this directive expresses that the patient who has given biological material that has served as the basis of an invention or has been used by this latter, must give its free and informed consent as regards the filling of the patent application on such invention, according to its national law. Unfortunately, the fact that this provision has been inserted in the recitals and not in the articles of the directive jointly with the fact that, in some European countries, the national state authorities have found this provision controversial and too advanced, have more or less emptied this principle at the directive's implementation level. However, even if the patient's consent is not a condition to patentability according to some member states' patent law, the privacy and secrecy laws still apply, and one could wonder whether solely on those grounds, the consent of the patient to such use of part of his body does not remain mandatory. This sometimes called "misplaced" ethical rule, present in the recitals of the directive, remains therefore a reference that must be taken into account when tackling the issue of filing patents on biotechnological inventions.

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[1] Art. 2 of the Berne convention for the protection of literary and artistic works of 9 September 1886.
[2] Cfr. POULLET, Yves, "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, pp. 301-319.
[3] DITTMANN, Volker. Directives de l'ASSM relatives à l'utilisation des biobanques – jalons dans la perspective de la loi. Séance de réflexion « Biobanques – Au Carrefour entre les intérêts de la recherche et la protection des données », 24 octobre 2005, Berne.
[4] Recital 17 and article 1, paragraph 2 of Directive 96/9/EC of the European Parliament and of the Council of 11th March 1996 on the legal protection of databases, *OJEU L 077,* 27th March 1996, pp. 20-28.
[5] Article 7, paragraph 5 of Directive 96/9/EC of the European Parliament and of the Council of 11th March 1996 on the legal protection of databases, *OJEU L 077,* 27th March 1996, pp. 20-28.
[6] ECJ, 9th November 2004, *Fixtures Marketing Ltd v. Organismos prognostikon agonon podosfairou AE (OPAP)*, 444/02, Rec., p. I-10549. Paragraphs 49 to 52. See also ECJ, 9th November 2004, *The British Horseracing Board Ltd and Others v. William Hill Organization Ltd.*, 203/02, Rec., p. I-10415.
[7] Isolation of the samples in order to be identified, purified, classified and reproduced outside the human body. Recital 21 of Directive 98/44/EC of the European Parliament and of the Council of 6th July 1998 on the legal protection of biotechnological inventions, *OJEU L 213*, pp. 13-21.
[8] There is the exception for research purposes.
[9] Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions, *OJEU L 213*, pp. 13-21.