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Digital therapeutics: What protection does intellectual property offer?

Digital therapeutics innovations are booming, driven by AI, open data and the convergence of technologies. Finding the best angle to protect and promote these inventions requires a holistic approach. This study provides an overview of tools and best practices.

From wearables that monitor diabetes to clinical decision support systems, healthcare data mining software solutions and robotic surgery, digital therapeutics connects medical devices and pharmaceutical products to the world of data and artificial intelligence (AI). The innovations to be protected are numerous, while intellectual property has difficulty protecting certain key elements such as processes, AI training data, parameters, or algorithms[1]. These innovations also have short life cycles, so they can be "moving targets" for IP. This study provides an overview of protection tools.

1. Copyright and *sui generis* database right: a form of protection to not overestimate

Copyright and *sui generis* database right have the advantage of being obtained without applying, provided that the conditions are met. But these protections have their limits.

A. Copyright

Subject matter of protection. - In a digital therapeutics device, copyright can protect graphic interfaces and integrated multimedia elements (sound, text, image). The look and feel of a telehealth application could, for example, benefit from this protection.

Regarding software, only their expression is protected by copyright, i.e., the code and preparatory design work (including functional and organic analyses, flow charts, internal and external specifications, and functional architecture[2]). On the contrary, "*ideas and principles which underlie any element of a computer program*" are not protected[3]. Thus, copyright does not protect algorithms[4], functionalities, programming language, data file format[5] or methods[6].

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[1] J.-M. Deltorn, "Proprietary Issues in Data and Learning Models - Protecting AI Applications through Intellectual Property", *5e Forum Industriel en Intelligence Artificielle (FIIA),* 2020.
[2] French Agency for the Protection of Programs, "Specific copyright protection for software", 2018.
[3] EP and EU Cons., Directive 2009/24/EC, 23 Apr. 2009, on the legal protection of computer programs, art. 1, 2°.
[4] *Cour de cassation*, 1rst civil chamber, 14 Nov. 2013, No. 12-20.687.
[5] CJEU, 2 May 2012, C-406/10, *SAS Institute Inc. v. World Programming Ltd.*
[6] Paris Court of first instance, 14 June 2002, Paris Court of appeal, 5 Apr. 1993.

As for databases, only their structure (architecture or arrangement) is copyrightable, not their content. Copyright protection of the data itself, which is at the heart of the value creation of digital therapeutics companies, is far from certain. In practice, a distinction is made between raw and processed data, i.e., "*information that is organised, interpreted, contextualised and sometimes enriched for specific purposes*"[7]. However, it has been ruled that "*raw information cannot be considered copyrightable*"[8]. If they encompass intellectual works, processed data could be eligible for copyright protection. This could be the case, for example, regarding health data modified or restructured by healthcare professionals, but the originality requirement often remains a significant obstacle to copyright protection.

Conditions of protection. - Copyright protection is subject to an originality requirement, defined by case law as the imprint of the author's personality. This criterion, which was initially developed for fine arts, does not seem well adapted to digital therapeutics technologies. It has been adjusted for software and databases, but some legal uncertainty arises from the abstract terms used in case law. For software, the famous *Pachot* ruling of 1986 states that software is original when it bears the imprint of its author's intellectual contribution and is the result of a personalised effort going beyond the mere implementation of an automatic and binding logic[9]. It will be necessary to check whether the developer's choices show "*his/her own intellectual contribution and a personalised effort*"[10]. Regarding databases, the Court of Justice of the European Union (CJEU) considers that "*criterion of originality is satisfied when, through the selection or arrangement of the data which it contains, its author expresses his creative ability in an original manner by making free and creative choices*"[11]. In line with this case law, French courts do not take into account the efforts and know-how devoted to the creation of the data itself[12].

Limitations related to open data and open source. - Open data and open source may also limit copyright protection.

To develop open data, a transposition order dated 24 November 2021 extended the Text and Data Mining exception, which is defined as the "*implementation of an automated analytical technique aimed at analysing text and data in digital form in order to generate information, including patterns, trends and correlations*"[13]. This is one of the steps in deep learning systems[14]. Initially, this copyright exception was limited to mining carried out for public research purposes, excluding any commercial purpose. From now on, any person, for any purpose (including commercial purposes), may reproduce a work/software for text and data mining purposes, provided that the work/software has been lawfully accessed. The practical impact of this exception for digital therapeutics companies is still uncertain, as disclosure of the work seems to be a criterion for benefiting from the exception[15]. Thus, if access to the work has been obtained under the seal of confidentiality, e.g., in the context of a consortium agreement, the "mining" exception should logically be excluded.

Moreover, digital therapeutics companies often use open-source bricks to develop their solutions. Such "bricks" are software components that can be used, copied, modified, and distributed without the owner's permission, under the terms of an open-source licence. However, some open-source licenses, such as GPL v3, can contaminate software, i.e., improvements or new applications made from the open-source software must be shared and will also be subject to the terms of the open-source license. This often implies a loss of value for the technology[16].

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[7] Movement of the Enterprises of France (MEDEF), "Data strategy as a source of value for the company", Sept. 2021.
[8] Paris Court of first instance, 24 March 2010, No. 08/12969.
[9] *Cour de cassation*, Plenary Assembly, 7 March 1986, *Pachot*.
[10] *Cour de cassation*, 1rst civil chamber, 17 Oct. 2012, No. 11-21.641.
[11] CJEU, 1 March 2012, C-604/10, *Football Dataco Ltd and others v. Yahoo! UK Ltd and others.*
[12] See in particular Paris Court of Appeal, 27 Oct. 2015, No. 14/14239.
[13] Ord. No. 2021-1518, Nov. 24, 2021, transposing Directive (EU) 2019/790 of 17 April 2019 on copyright and related rights in the Digital Single Market, creating Articles L. 122-5-3 and L. 122-6-1, VI of the French Intellectual Property Code.
[14] J.-M. Bruguières, "Artificial intelligence and copyright - Moving away from the science fiction of "machines/authors" to the reality of data law", *Communication Commerce Electronique*, 2020, study 11.
[15] "*When the work has been disclosed, the author cannot prohibit* (...)" (French Intellectual Property Code, art. L. 122-5).
[16] A. Dureuil, "Six points of vigilance for contracting around artificial intelligence", Mind Health, 9 Oct. 2018.

B. *Sui generis* database right

Subject matter of protection. - The *sui generis* database right makes it possible to protect databases without applying the copyright criteria. Thus, the collection of learning data used by a digital therapeutics technology incorporating AI could be protected. But the data is not protected as such: only extraction or re-use of a qualitatively or quantitatively substantial part of the content of the database can be prohibited.

Conditions of protection. - For the content of the database to benefit from protection, its obtention, verification or presentation must demonstrate a substantial financial, technical, or human investment[17]. Paris Court of Appeal recently recognised the protection of the real estate advertisements' database on the website "leboncoin.fr"[18].

However, according to European case law, only the resources devoted to searching existing elements and collecting them are taken into account, excluding the resources used to create the database content[19]. Consequently, protection seems limited to databases that gather pre-existing data from external sources, since databases that gather data created by the database producer do not, in principle, meet the substantial investment criterion.

Digital therapeutics companies should therefore be aware that this *sui generis* right will not allow them to protect "*data produced by machines, Internet of Things devices, metadata or data resulting from [AI]*"[20], nor the models used in AI, i.e., the set of parameters resulting from learning[21].

New protection limits. - A recent CJEU decision drastically reduced the scope of the *sui generis* right by adding a new criterion for the protection: extractions and re-uses of database's contents are only prohibited if they have the effect of depriving the right-holder of income which would enable him/her to redeem the cost of the investment in obtaining, verifying and presenting the database content [22]. As an author pointed out, this new criterion is likely to encourage, in practice, database producers to turn away from the *sui generis* right in favour of common law, as parasitism, for example, is easier to claim[23].

Furthermore, the transposition order dated 24 November 2021 also extended the Text and Data Mining exception to extractions, copies or digital reproductions of databases made by any person, for any purpose, even commercial. Here again, the exception appears to be limited to databases "*made available to the public*"[24], excluding the databases access to which has been obtained under the seal of confidentiality, so the impact for digital therapeutics companies seems limited.

2. Patents: a form of protection to consider

Digital therapeutics start-ups' first application is often a trademark application on the name of the company, product, or service. As part of an overall consideration of asset value creation, other applications should be considered. Design rights can, for example, protect the graphic interface of a telehealth application or the design of a connected scale. Patenting should also be considered: it reassures investors by giving a quantifiable value to the technology and represents a barrier for competitors, who cannot use the same invention, even if developed independently. Contrary to some preconceived ideas, exclusions from patentability are not an insurmountable obstacle to the patentability of digital therapeutics innovations, even if the protection of inventions incorporating AI has its own particularities.

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[17] French Intellectual Property Code, art. L. 341-1.
[18] Paris Court of appeal, 2 Feb. 2021, No. 17/17688.
[19] CJEU, 9 Nov. 2004, C-203/02, *The British Horseracing Board Ltd et al. v. William Hill Organization Ltd.*; CJEU, 9 Nov. 2004, C-46/02, *Fixtures Marketing Ltd v. Oy Veikkaus Ab.*
[20] S. Chatry, "Database producers rights", *JurisClasseur Propriété littéraire et artistique, fascicule 1650*, citing 'Evaluation of Directive 96/9/EC on the legal protection of databases', SWD (2018) 147 final, p. 15 and p. 24.
[21] J.-M. Deltorn and G. Leménager, "The protection of artificial intelligence in France and Europe", *Réalités industrielles, Annales des Mines*, Nov. 2020.
[22] CJEU, 3 June 2021, C-762/19, *CV-Online Latvia.*
[23] J. Larrieu, "Databases: sui generis right at risk?", *Propriété industrielle*, 2022, communication 5.
[24] French Intellectual Property Code, art. L. 342-3.

A. Exclusions from patentability

Diagnostic methods. - Some digital therapeutics innovations aim to make a diagnosis, e.g., a software using AI to interpret X-rays. Under European law, diagnostic methods practiced on the human or animal body are excluded from patentability. The aim is to prevent a practitioner from being unable to diagnose a patient because of a patent right. But digital therapeutics companies should not overestimate the scope of this exclusion.

First, only methods that have all the following characteristics are excluded from patentability: an examination phase, a comparison of the data with standard values, the finding of any significant deviation and a deductive decision phase. "*Only methods the result of which directly allows a decision to be made about the medical treatment to be carried out will be excluded*"[25].

Most importantly, only method claims fall under the exclusion. The exclusion does not apply to substances and apparatus for carrying out these methods[26]. Therefore, claims to medical devices, computer programs or storage media are potentially patentable[27]. Accordingly, in digital therapeutics, the device itself, e.g., a wearable measuring blood flow and using the data to diagnose a cardiovascular problem, may be protected. It is more difficult to patent the software and method included in the device, but it is possible if the claim focuses on how the data is collected, analysed, and processed, without reference to the diagnosis[28].

Computer programs and mathematical methods. - Under European law, computer programs, mathematical methods, schemes, rules and methods for performing mental acts are excluded from patentability. For the INPI (the French IP Office)[29] and the EPO[30], artificial intelligence is a computer-implemented mathematical method as it is based on computational models and algorithms "*for classification, clustering, regression and dimensionality reduction*". However, these exclusions are not insurmountable obstacles to the patentability of digital therapeutics innovations, even when they incorporate AI.

Indeed, computer programs and mathematical methods are only excluded from patentability if they are claimed "as such". If the characteristics of the claim are only abstract (for example, a classification process using machine learning), it is devoid of technical character and excluded from patentability. On the contrary, a computer program is protectable if it produces a further technical effect beyond the normal physical interactions between the program and the computer. For example, software controlling a dialysis machine or processing physiological data from sensors can be patented[31]. Above all, a distinction must be made between "computer programs" and "computer-implemented methods" which involve technical means (the computer) and therefore have a technical effect[32]. Similarly, a claim to a mathematical method involving technical means or to a device is not excluded from patentability[33]. Mere reference to a physical system, such as a computer, overcomes the exclusion[34], and it is at the stage of assessing inventive step that a distinction will have to be made between the technical and non-technical features of the claim (see below).

A technical effect is unlikely to be recognised where the software has a purely organisational purpose, such as automatically sending a diagnosis to a doctor[35]. Conversely, the use of a neural network in a heart monitoring device to detect irregular heartbeats would be patentable[36].

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[25] J.-C. Galloux, J. Azéma, *Droit de la propriété industrielle*, Dalloz, 8th ed. , 2017, p. 193.
[26] French Intellectual Property Code, art. L. 611-16.
[27] EPO, Guidelines for Examination, Part G, Chapter II, 4.2.
[28] P. Sadler, Z. Mummery, "Innovations in digital healthcare - navigating patent challenges", Med-Tech news, 2 August 2021.
[29] INPI, Guidelines for the Grant of Patents, 2020.
[30] EPO, Guidelines for Examination, Part G, Chapter II, 3.3.1.
[31] P. Sadler, Z. Mummery, op. cit.
[32] EPO, Guidelines for Examination, Part G, Chapter II, 3.6.
[33] EPO, Guidelines for Examination, Part G, Chapter II, 3.3.
[34] J.-M. Deltorn, "Patentability - Patentability of artificial intelligence and machine learning applications: the practice of the European Patent Office", *Propriété industrielle*, 2019, file 4.
[35] P. Sadler, Z. Mummery, op. cit.
[36] EPO, Guidelines for Examination, Part G, Chapter II, 3.3.1.

B. The particularities of patenting inventions that incorporate AI

The development of AI raises new issues for intellectual property offices. These are all particularities that digital therapeutics companies need to be aware of when considering patenting inventions that incorporate AI.

Designation of the inventor. - It is now established that an AI system cannot be designated as inventor in Europe. On 21 December 2021, the EPO Board of Appeal upheld the decisions that rejected applications in which the designated inventor was the AI system DABUS[37]. While the USPTO has ruled similarly, contrary decisions exist, e.g., in Australia and South Africa.

Sufficiency of description. - In the patent, the invention must be sufficiently described for it to be carried out by a person skilled in the art. This raises new questions regarding AI. To patent an invention incorporating AI, it is necessary to describe the input data, the output data, the type of AI (neural network, genetic algorithm, support vector machine, etc.), the internal architecture and its possible learning[38].

The untrained algorithm may thus have to be disclosed, as well as the training data it will have to use. For example, a patent application for a method of determining cardiac output from blood pressure, by the aid of an artificial neural network whose weighting coefficients are determined from learning, was rejected because the training data was not sufficiently described[39]. According to an author, description should be considered sufficient when "*detailed information is provided on the methodologies for source selection and for processing data specifically tailored to enable the person skilled in the art to obtain training data suitable for the intended purpose*"[40].

Inventive step. – As mentioned, offices treat AI as mathematical methods, and the mere mention of a computer overcomes the exclusion from patentability. However, when assessing inventive step, the EPO only takes into account features that contribute to the technical character of the invention[41]. A method only contributes to the technical character of an invention (i) when it serves a technical purpose or (ii) when it is adapted for a specific technical implementation. Thus, an AI method has a technical purpose when the algorithmic step contributes to the solution of a concrete technical problem[42]. The EPO will consider the AI method to be adapted for a specific technical implementation when it is specifically adapted to the internal functioning of the computer[43]. In this case, the algorithmic step has a technical character and will be taken into account in the examination of inventive step.

Despite these particularities, digital therapeutics companies should not overestimate the difficulty in patenting inventions that incorporate AI. For example, a heart monitor controlled by a neural network specially adapted to limit the number of false identifications was considered patentable[44].

3. Contracts: a form of protection to be built and maintained

A. Contracts for trade secret protection

Digital therapeutics companies frequently collaborate with third parties: health institutions, research institutions, consultants, third-party companies, etc. Whether they are academic or economic partners, confidentiality must be ensured from the beginning of the negotiations to the end of the project, and even beyond. This is one of the conditions for benefiting from trade secret protection.

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[37] EPO Receiving Section, 27 Jan. 2020, J 8/20, and J 9/20; EPO Board of Appeal, 21 Dec. 2021.
[38] O. Rocher, "3 questions - Industrial property and AI", *La Semaine Juridique – Entreprise et affaires*, 2020, 27.
[39] EPO, Receiving Section, T 0161/18, 12 May 2020, *Äquivalenter Aortendruck v. ARC Seibersdorf.*
[40] F. Hagel, "Learning data, the Achilles heel of inventions incorporating AI", *Propriété industrielle*, 2021, study 2.
[41] EPO, Guidelines for the Examination Performed, Part G, Chapter II, 3.3.
[42] J.-M. Deltorn, op. cit.
[43] J.-M. Deltorn, op. cit.
[44] EPO, Receiving Section, T 0598/07, 19 May 2010.

Purpose and limits of protection. - Trade secrets can protect raw or processed data and databases. For example, digital therapeutics companies could benefit from protection of the training data used in their AI systems. Trade secrets can also protect algorithms, codes, processes, parameters, etc. However, trade secrets are more difficult to defend and enforce than traditional forms of intellectual property because they rely on a civil liability system, not on a property right. Thus, the unlawful acquisition, use or disclosure of trade secrets is punishable, but the independent discovery of the same information remains lawful. For example, it is not possible to prohibit a competitor from independently creating the same AI system.

Conditions of protection. - To benefit from trade secret protection on information, whatever their nature, digital therapeutics companies must ensure that three conditions are met.

First, the information must be *secret*, i.e., not generally known or readily available to persons that are familiar with this type of information. Companies should therefore not rely on this protection if the information is likely to be disclosed solely as a result of the commercialisation of the digital therapeutics product. It may also be risky to include algorithms or trade secrets in standard operating procedures (SOPs) or marketing documents, or even in patent applications.

Information should also be subject to *reasonable protection measures to preserve confidentiality*. Good practices for protecting confidentiality include classifying information according to different levels of confidentiality, marking files and folders and training employees regarding confidentiality protection. Within the company, the implementation of an information access policy on a need-to-know basis allows to limit access to information to only those employees who have a need to know, with a procedure for authorising and controlling access to premises, to files on computer networks, etc. Reasonable protection measures to preserve confidentiality are also built with contracts. Non-disclosure agreements (NDA) must be signed before any disclosure is made in the context of contract negotiations, whether with potential suppliers, customers, partners, or investors. Confidentiality clauses in research and development (R&D) contracts are essential. The duration of confidentiality after the end of the contract should be adapted according to the sensitivity and obsolescence of the information exchanged.

Finally, the information must have *commercial value.* This condition could be an obstacle to data's trade secret protection. In digital therapeutics innovations, the value is most often the result of the combination of data, in particular the learning data used by AI systems, and it might be difficult to find commercial value in isolated data. The contract therefore appears to be an additional tool for protecting data.

B. Contracts for regulating data access and use

The validation of contractual restrictions by the *Ryanair* case. - Data is the core value of many digital therapeutics companies, but as mentioned, the tools for protecting these data are imperfect. Contracts therefore appear to be the solution for regulating access and use of data, as illustrated by the *Ryanair* ruling[45]. In this case, the airline Ryanair objected to the use, by PR Aviation, of the data displayed on its website, not on copyright or *sui generis* rights' grounds but on the ground of its general terms and conditions. The CJEU held that the creator of a database not protectable by copyright or *sui generis* right may establish contractual limitations on the use of the database by third parties, as provisions on the rights of the legitimate users of databases are not applicable. As an author pointed out, it is important to ensure that the general terms and conditions are accepted by users, since simply putting them online is insufficient to make them enforceable[46]. The contract thus appears to be an essential tool for controlling access to and use of publicly available data, such as in the *Ryanair* case, but also of data exchanged under data access agreements or R&D contracts.

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[45] CJEU, 15 Jan 2015, C-30/14, *Ryanair Ltd v. PR Aviation BV.*
[46] J.-M. Bruguières, op. cit.

Data access agreements. - Signing data access agreements enables digital therapeutics companies to secure a right of access to data that are essential for the operation and improvement of their technologies, especially when they incorporate AI. In practice, agreements are signed between software publishers and healthcare institutions, so that the publishers can use the personal or anonymised health data held by the healthcare institutions, in order to train their AI systems. Following the classic scheme provided for in these agreements, the platform and the algorithm are made available free of charge to the healthcare institutions by the publishers, who in return benefit from an access right to the data[47]. The ownership and use rights of the input data, both raw and processed, as well as of the data and models resulting from the learning process, must then be determined contractually.

R&D contracts. - It is up to digital therapeutics companies to make use of contractual flexibility to determine, by contract, the ownership and use rights of the data brought to and resulting from R&D projects. First, companies bringing data to a joint project must contractually claim them by listing them among their "background information", which they will retain ownership of at the end of the project. Then, the access and use rights of their data by the other partners must be regulated. In practice, each partner will benefit from a free licence on the "background information" of the others for the needs and duration of the project, but it is possible to contractually limit access to certain data, e.g., by prohibiting its partners reverse engineering. Finally, the companies must ensure that they retain ownership, or co-ownership, of the data resulting from the common project. It is advisable to negotiate, at the very least, an access and use right to the data they need to operate and improve their technologies, in particular to train their AI systems.

The contract therefore appears to be the central pillar of a multifactorial protection of digital therapeutics innovations, the value creation of which is based on copyright and *sui generis* database right, to a certain extent, but also on patents, contrary to some preconceived ideas.

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[47] A. Dureuil, op cit.