Algerian Journal of Legal and Political Sciences__Vol 58 , N°02., year:2021,page : 928 –954

In quest of the legal dimensions for the protection of Big Data after Corona Pandemic: The case of intelligent health inventions

البحث عن الأبعاد القانونية لحماية البيانات الضخمة بعد جائحة كورونا: حالة الاختراعات الذكية المتعلقة بالصحة

Nadjiba BADI BOUKEMIDJA
Lecturer at University of Algiers-1
Benyoucef BENKHEDDA,
Faculty of Law, Algiers, Algeria
Email : n.boukemidja@univ-alger.dz

Received	Accepted	Published
2021-03-30	2021-05-12	

Abstract:

Following the evolution of artificial intelligence which influenced several fields, including the field of health, we find the subject of the legal protection of the inventions that pertain to health, which imposes the consideration of the information, given that the principle, in this case, is the right of information, in particular at the time of obtaining a patent of the invention which supposes the disclosure of the confidentiality related to the inventive idea, except that in parallel this information is related to the personality of its owner. Therefore, the third party cannot gain access to it, because of this fact one is faced with personal information.

Key words: artificial intelligence, data, inventions, health, privacy.

الملخص:

نظرا للتطور الذي يشهده الذكاء الاصطناعي والذي مس ميادين عدة، من بينها ميدان الصحة. نجد موضوع الحماية القانونية للاختراعات المتعلقة بالصحة، والتي تفرض مراعاة الشق الخاص بالمعلومات، باعتبار أن المبدأ يتمثل في حرية المعلومة، خصوصا عند الحصول على براءة الاختراع التي تفرض إفشاء السرية المتعلقة بفكرة الاختراع، إلا أنه من جانب مقابل نجد هذه المعلومات مرتبطة بشخص صاحبها، ولا يجوز للغير التوصل إليها، باعتبارها معلومات شخصية.

In quest of the legal dimensions for the protection of Big Data after Corona Pandemic: The case of intelligent health inventions

الكلمات المفتاحية: الذكاء الاصطناعي، المعلومات، الاختراعات، الصحة، الحياة الخاصة.

* **corespondant author : Nadjiba badi boukemeja**

Introduction :

Over the last decade, there has been a great number of technological advances in the field of AI and data sciences. Although research on AI for various applications has been ongoing for several decades, the current wave of AI hype is different from the previous ones[1].

The digital revolution has the potential to improve healthcare quality. It has created new technology in order to tackle large data sets, solving complex Problems that previously required the involvement of human intelligence. Artificial Intelligence has the potential to analyze immense volume and variety of data. It improves the capacity to collect vast amounts of information as it has led to the intervention of machine learning and big data analytics[2].

In the cyberspace, the big data are analysed by artifcial intelligence (A.I), and the analysis results are fed back to humans in the physical space in various forms. In sum, the Fourth Industrial Revolution promises to enhance the distributed knowledge of a system drastically, while decreasing the role of human decision-makers. Technology would be on the verge of creating an intelligence "external to humans". This would, eventually, give rise to a second economy Massive fows of sensible data gathered with the help of ubiquitous sensors and

[1] Adam BOHR, Kaveh MEMARZADEH, The rise of artificial intelligence in healthcare applications, Artificial Intelligence in Healthcare, 2020, pp 25-58

[2] -Garima GUJRAL, Artificial intelligence (AI) and data science for developing intelligent health informatics systems, National Conference on AI in HI & VR, SHSS-TISS Mumbai, August 30-31, 2019.

evolving machines would make intelligence an outcome of densely knitted artifcial agents[1].

Digital technologies, which have already profoundly transformed our daily lives, are now paving the way for new medicine. Tomorrow's medicine will no longer resemble the one we use on modern times: it will be more preventive, more personalized, driven by innovations in fields as diverse as the processing, analysis, and storage of health data, artificial intelligence and machine learning, connected objects, robotics and virtual reality.

This transformation represents an opportunity for our health care system to change and improve. By promoting the emergence of precision medicine, it will improve the services provided yo to patients. The use of these exceptional tools, enhanced by advances in medicine, harbors the hope of healing, preserving, and improving our health and quality of life more generally.

The integration of artificial intelligence would cause the healthcare system to be more focused on prevention, the health path - from medical to medico-social - as well as the quality of care by opting for a global approach to health. The hospital will be refocused on high-value-added activities, with high-performance technical platforms and better-coordinated healthcare that account for the specificity of each individual[2].

Thus, the problem is concerned with the limits of the legal protection of intelligent inventions related to health.

The answer to the problem requires the implementation of a descriptive approach in order to shed light on certain essential concepts. Likewise, a comparative approach is needed to address the contrast between the international and national texts.

---

[1] - Mario BENASSI, Elena GRINZA, Francesco RENTOCCHINI, The rush for patents in the Fourth Industrial Revolution, Journal of Industrial and Business Economics, May 2020, pp 01-30.

[2] - Agnes BUZYN, Innovation at the service of our health care system. Voices of research, December 2018,p. p02.

Finally, the answer to this issue requires the use of an analytical approach, through which a set of solutions and suggestions is proposed.

This research paper is framed around the following plan:

Section I -Health data and intelligent inventions

A– The limits of health data protection
B-The traceability of health data

Section II: Intelligent health inventions in the field of intellectual property

A-The primacy of the public interest
B-Inalienable intervention of intellectual property rights

Section I -Health data and intelligent inventions:

Intelligence in the health field like any other intelligence, is confronted with big data, and more precisely in relation to invention(A), which leads us to the importance of the traceability of dig data in this area, in order to conclude the possibility of legal protection(B).

A– The limits of health data protection

Modern healthcare systems pivot from being volume-based to being value-based systems, which is putting an increasing demand to exploit health data for resource optimization, improved care quality, patient satisfaction, and health outcomes[1].

Data constitutes the essence of the practice of medicine in its relationship with the patient. It is, therefore, not surprising, in

[1] - Syed Sibte RAZA ABIDI, Samina RAZA ABIDI, Intelligent health data analytics: A convergence of artificial intelligence and big data, Healthcare management forum, 2019, pp 01-05.

the context of global digitization of the entire medical practice and the use of more numerous and varied captors to witness an exponential increase in the quantity and diversity of the available data.

The sources of health data are manifold: medico-administrative databases, patient care information, images of diagnostic procedures performed each year, registries, medical records, clinical trials, patient data collected via smartphones, social networks, Internet sites, …etc.

In essence, all the data are disparate and are organized in a wide variety of formats, because they have been collected for some specific purposes: to diagnose a disease, detect a particular mutation in the genome, reimburse for care, measure physical activity, etc.

Artificial intelligence (A.I) revolutionizes data by seeking to use of all this data to advance research on health issues, healthcare and innovation.

It does this by annotating and matching data to obtain highly reliable results and with a better quality, but also to bring out hypotheses and links that were not envisaged. One condition is needed: collect enough usable data to maintain the A.I. algorithms.

When we consider that nearly 100,000 images are needed for A.I. algorithms to learn how to detect melanoma and make a reliable diagnosis, it is clear that a single hospital cannot collect the necessary quantity of data on its own. That said, data producers must work together to collect, exchange and share their data. It is also necessary to ensure that "clean" data are available, stored, and well-labeled[1].

Also, mobile health is defined as the practice of applying mobile-based devices such as the mobile phones, patient monitoring devices, personal digital assistants (P.D.As), and

[1] - Cedric VILLANI, Health and Artificial Intelligence, National Health Insurance Plan Information System. Paris: NRC, 2018.

other wireless devices for the medical and public health. Therefore, this process requires the application of one of the most important benefits of mobile phone, commonly called the voice and short messaging service (SMS). Nowadays, there are more than 500 research projects about the m-health, and nearly 40,000 medical-based mobile applications available worldwide[1].

It should be noted that there is no single area of health, that is revolutionized by artificial intelligence and Big Data. The example of radiologists is illustrative. In the United States, there are approximately 800 million radiological examinations performed each year, generating 60 billion images, an enormous bank of information allowing more precise diagnoses to be made. IBM Watson, among others, has thus been able to detect cases of pneumonia better than doctors.

In addition, the examples could be multiplied ad infinitum. Artificial intelligence systems in the medical world have access to millions of medical records and allow much more individualized diagnoses more than what doctors can make. No physician, be him a general practitioner or specialist, would be able to ingest such a large quantity of data[2].

The fundamental point for the quality or robustness or even the certification of a statistical learning algorithm is, by all means, the quality of the available data, as well as their representativeness of the field of study or the application. Are the training data of the algorithm well representative of all the situations, or are there any potential cases which are likely to be encountered subsequently during the operation of the algorithm?

One of the raised questions and issues pertains to anticipating the generalizability of its use. Indeed, if groups or situations are absent or simply under-represented - that is, if the data is biased in one way or another - the model or the resulting

[1] - Faizal KHAN, Sultan Refa ALOTAIBI, Applications of Artificial Intelligence and Big Data Analytics in m-Health: A Healthcare System Perspective, Journal of Healthcare Engineering, 2020, pp 01-15.
[2] - Serge SOUDOPLATOFF, Artificial intelligence: expertise everywhere accessible to all. Foundation for Political Innovation editions, February 2018.

algorithm will only reproduce the biases or will prove that it is incapable of producing correct predictions of situations, that it, it has not sufficiently learned during its training.

This problem is very well referenced in the literature and highlighted in ethical reports and guides. It is even an old problem already formalized in statistics for the constitution of a sample relative to a reference population in experimental planning or survey theory.

Just because the data are voluminous, already acquired, does not mean that everything must be taken into account, or that we should not worry about acquiring more data. Consider the typical example of forecasting rare but catastrophic events. A simple, not to say trivial, algorithm leads to a very low error rate, if it does not predict any occurrence of the rare event but is useless or even dangerous.

The experience of the data scientist then leads to over-representing - in other words: over-sampling - the rare events, or under-sampling the very frequent ones, or to introducing weights in the choice of the objective function to be optimized. These factors depend on the asymmetry of costs, to be evaluated by business experts, of a false positive or wrongly forecasting an exceptional event, relative to the cost induced by a false negative that does not anticipate the disaster [1].

Thus, security is essential in as much as it involves methods linked to cryptography and the knowledge of a secret that allows access to the data. In this case, the patient's file is totally encrypted, and only authorized persons (the patient, caregivers, etc.) must be able to read and modify it. Internationally certified for "Top Secret" classifications, the current algorithms offer sufficient guarantees to implement total confidentiality: "breaking" them would take years, if not decades, on the world's most powerful supercomputers.

[1] - Philippe BESSE, Legal and ethical implications of artificial intelligence algorithms in health care. hal-02424285v2, March, 2020, p. 09.

It is true that the power of processors is increasing, but these encryption methods are also adapting, to guarantee the best possible protection. Decryption involves a "secret" which will consist, for example, of the physical possession of an electronic device and a password. A classic "strong authentication" can be based on a password composed of a fixed part, known to the user, and an ephemeral, single-use part. It is generated by a small device, the size of a USB key or a credit card.

Also, security must include physical failures that ifluence the media containing sensitive data. A component may fail, one or more machines may be damaged during a fire, or more simply, a move.

The media themselves - disks, USB keys, magnetic tapes - can silently corrupt and affect the nature of the stored files. The multiplication of physical media, -a computer center contains several tens of thousands of disks and as many magnetic tapes-. So the increased probability of multiple and simultaneous breakdowns has led to the establishment of strategies to reduce their impact [1].

To this end, universities and public research have been driving innovation in this area since the earliest days, and in recent years the pace has accelerated even further.

By way of example, the Canadian government recently allocated $125 million to the development of AI research as part of the Pan-Canadian Artificial Intelligence Strategy1 . In the U.S., the Massachusetts Institute of Technology (M.I.T.) has invested $1 billion to establish a new interdisciplinary AI college.

Similarly, Start-ups and mid-size companies benefit from the wave of massive A.I. investments. In the second quarter of 2019, a new record level of financing for A.I. start-ups was reached with $7.4 billion invested, while total financing for the

[1] - Philippe DENIEL, Protecting health data, Ensuring the best protection. Voices of Research, December, 2018, p. 43.

last five years amounts to more than $66 billion for these companies[1].

At the same time, when a hospital center holds a patient's data with his or her consent, this data is used in the context of care or diagnosis. The legislation requires that the patient's authorization be sought again if the physician wishes to use the data for another project. This approach appears to be an obstacle to Big Data, which requires the largest and most complete mass of data possible to be made available. Getting the data out is not allowed by law, or only after the processes of anonymization and aggregation.

Nevertheless, these necessary processes, in principle, put forward by the National Commissions for Information Technology and Civil Liberties, result in the loss of the options for aggregating data at the individual level. Ideally, each citizen should be empowered to make decisions about the sharing of their data, whether it is medical or not. An in-depth education effort should be undertaken with citizens, so that each patient is aware of the potential use of their data, and is equipped to make an informed decision on whether, or not to propose them for research.

B-The traceability of health data

An innovation such as the blockchain tends to provide very timely solutions at a time when, quite rightly, patient consent is put at the heart of data access and use. The blockchain is a robust technology which, by distributing information over a very large number of machines, enables decisions or uses to be tracked around the data. Said differently, the blockchain is a technology that would allow this consent (or changes in this consent) to be solidly recorded. In the same way, this technology provides a precise directory of the use made of sets

[1] -Julien LACHERE, Trends in investment and patents in the field of artificial intelligence, Strategic file, Innovating to survive: are you a precursor or a follower? BCA, October, 2019.

of data: who uses which set? This question is important in the context of the emergence of A.I. learning based on separate sets[1].

Thus, the physician's role is not only to inform the patient about the use of A.I., but also to have the ability to intervene with the use of algorithmic treatment by modifying the parameters. In order for the physician to be able to make informed decisions, traceability of actions is provided. This man-machine interaction naturally raises the question of the physician's responsibility.

However, as long as the doctor remains at the center of the relationship of trust with the patient, he continues to assume an obligation to provide information, and remains in control of the choices and decisions made, the machine must be considered as a simple decision-making aid that does not replace the doctor and does not modify the rules of responsibility in any specific way.

In the current state, the rules of medical liability applicable to the physician are therefore not modified by the use of algorithmic treatment. In principle, the physician assumes an obligation of care which is an obligation of means, not of result. He is only liable in the event of a culpable error that has resulted in damage.

If the obligation to provide information about the use of an A.I. device does not cause any particular problem, it will probably be more difficult to guarantee that the physician will be able to inform the patient of the algorithmic "modalities of action of this treatment". However, the physician will need to understand this by himself. This, it must be noted, may be difficult or even impossible to attain in some situations. The conditions for deploying algorithms must therefore take these requirements into account, and private companies offering their AI systems will, then, have to explain or even train physicians in

[1] - Marco FIORINI, Artificial intelligence, innovative vectors, health2030, Leem, 2019, p. 45.

the proper use of these tools so that they, in turn, can, briefly, inform patients how they work.

Beyond the obligation to provide information, it seems relevant in any case that physicians should be able to master a minimum of these tools, so that they have confidence in their feasibility, and they become real decision-making aids [1] .

The legal regime specifically applicable to personal health data implies certain constraints concerning the use of health databases. The sensitivity of this data restricts the legal basis for processing, which is listed exhaustively by the Data Protection Act, concretized in Algeria by Law No. 18-07 of June 10, 2018, on the protection of individuals in the processing of personal data[2].

The prior information that must, in any case, be provided to individuals needs to specify the purposes for which the data will be processed, including the purposes for which artificial intelligence must be trained. If not, the use of the database for this purpose could be considered as a misuse of purpose.

Moreover, the massive processing of health data by artificial intelligence requires a prior study of the impact on the privacy of the persons involved, in accordance with the provisions of the new general regulation of data protection.

Finally, the provisions of the Public Health Code relating to professional secrecy stipulate that any person under the care of a professional, establishment or structure in the health, medico-social or social sector has the right to protect and preserve his or her private life and the right not to disclose any personal details.

According to the texts, the obligation of professional secrecy is an absolute principle and no one, not even the patient, can free the professional from it.

[1] - Philippe BESSE, op.cit, p. 09.
[2] - Official Journal, June 10, 2018, No. 34, pp. 10-20.

The dissemination of health data is not free, and the exchange or sharing of such data must be carried out with respect for professional secrecy, by circumscribing the circles in which the data may be communicated, with the prior consent of the patient or subject to his prior information, with the patient being able to exercise his right of opposition and objection.

Thus, the implementation of artificial intelligence within one or more health care institutions, using medical records as reference data, should respect the principles of exchange and sharing, particularly between separate care teams. Finally, treatments, which are conducted for research purposes or evaluation in the health field, tend to be subject to a complex authorization regime [1] .

We conclude that, although promising, Big Data in the health sector faces two major challenges. The first is political, since the method of remuneration for healthcare professionals is currently based on fee-for-service pricing and on the physical interaction between the professional and the patient. In other words, healthcare professionals are paid on the regular meetings they manage to organize with the patients.

Outside of the overall digital health offer, allowed by Big Data excludes this interaction most of the time, creating a significant bias in the promotion of dematerialized services. How can we hope to include healthcare professionals when their remuneration is not even provided for by e-health?.

In addition, the evolution of mentalities and the implementation of a more flexible mode of remuneration based no longer on physical interaction but on the care itself will certainly reduce this bias. To this end, the subject of reimbursement for teleconsultations has been raised in some countries, such as France in 2018. The latter demonstrated a desire for change and progress.

[1] -Laurraine MAISNIER-BOCHE, Artificial intelligence and health data. Journal de Droit de la Santé et de l'Assurance Maladie, Number 17 – 2017,p. 25.

The second component that challenges Big Data is the technological component. As we have explained in previous sections, interoperability is an essential aspect for the creation of relevant data aggregates, because they allow us to contextualize these data, and to create or develop the analytical tools needed to process them.

This is the key to the added value. Apart from health data, coming from various sources and existing in different formats, the health data sector is still fragmented (in silos), and while some of the silos are large, it is the coming together of these silos into super-aggregates of data that gives Big Data its full economic potential. In fact, data professionals believe that data aggregation will become a full-fledged business in the near future. This will change the current operation based on the collection, transfer, storage, and exploitation of data contained in the silos. This should eventually solve the problem of interoperability, and further, reveal the potential of Artificial Intelligence[1].

In essence, the lack of digital records and processes poses significant challenges for the adoption of AI solutions not just because data are needed to feed the algorithms, but also because staff frustration about the inadequacies of existing digital systems can lead to a reluctance to adopt more innovative and futuristic A.I solutions.

Either way, it is critical to get the basic digitisation of systems and data and the development of digital skills in place before launching the A.I efforts. Systematising digital data collection, linking datasets between systems and ensuring data cleansing are performed routinely.

These three operations are essential prerequisites for the introduction of A.I solutions. However, there is oftediscrepancy

[1] - Dimiter DIMITROV, Medical Internet of Things and Big Data in Healthcare. Health Inform Res, n°63, 2016, p. 156.

between the aspiration for complete clean data, and the reality that most healthcare organisations deal with[1].

As a result, the importance of patents in the health field is not in question, and having relevant patents can also make a company more attractive for acquisition and potentially increase its value. In the case of complex technology such as A.I., patents can serve as a tool to inform investors that credible research and development has been carried out.

While this may seem counter-intuitive, patents can actually facilitate collaboration with other companies. After filling in the patent application, a start-up company will be able to disclose its invention to others and protect it from any possible violations of copyright from any other person or company.

Patents can also be used to formalize a collaboration or licensing framework for the underlying technological developments. This can particularly be useful for start-up A.I. companies that wish to collaborate with larger companies.

Ultimately, holding a strategic patent portfolio will help a growing company maintain higher margins, discourage competitors from entering the market and deter them from suing for patent infringement. Investing in patents as early as possible can help a start-up A.I. company lay the foundation for a long-term competitive advantage[2].

Section II: Intelligent health inventions in the field of intellectual property

The issue of intellectual property is tightly connected with other problems that pertain to the idea of the exclusivity of the exploitation of the invention, provided that it belongs to its owner (A). Neverthless, this right does not need to exist before certain exceptional situations, such as those related to diseases

[1] - Mc Kinsey and company, Transforming healthcare with AI. The impact on the workforce and organisations, European Union, March 2020.
[2] -Julien LACHERE, op.cit.

and pandemics in the society, and which imposes the recourse to the case of a compulsory license for the public interest (B).

A-The primacy of the public interest

When researchers think about the needs of people at the bottom of the economic pyramid, most people think that the way to do it is to copy what works in high-income countries and reduce the cost.

"Affordability" is certainly a factor to consider in work of this type. However, "relevance", the question of whether the invention will actually address the problem in the context in which it is to be used, and "accessibility", the ability of the intended users to use and extend the invention on a large scale, are other essential strategies. We consider them to be the three essential elements of success.

If an invention meets these three criteria in the context of a "large" problem, it will be likely to be widely applied, and would have an impact on the whole population. Sometimes, these inventions prove to be better solutions for everyone, regardless of income level. While they were originally intended to address the needs of low-income populations, some of these "reverse innovation" inventions can result in a technological leap across an entire sector[1].

For example, Global Good refers to investigating an A.I. based ultrasound system in which a deep-learning ultrasound device can automatically detect the onset of pneumonia and its progression, or response to treatment, with better predictive value than current conventional means using radiography and human specialist interpretation.

Also, A.I.M.E. (Artificial Intelligence in Medical Epidemiology) is an American company created in partnership with GOOGLE researchers in order to try to detect epidemics carried by insects three months before they actually occur.

[1] - Michael VECCHIONE, Technologies for social good - an innovative approach, machine learning for a 5G future. 10th ITU Academic conference, 26-28 November 2018, Santa Fe , Argentina.

Tested in Brazil and Malaysia, A.I.M.E. detected the start of an epidemic of the ZIKA virus and dengue fever with almost 90% accuracy. The algorithm uses weather, urbanization, dengue mortality to create a probable area of spread.

The advantages of the medical information health A.I should be popularized for the elderly, and the elderly people can experience the convenient service brought by the medical information platform. The elderly can understand their physiological parameters at home and operate easily.

Trough A.I remote consultation, the space distance is greatly shortened, online consultation and diagnosis services for elderly people and doctors have provided, and the self-health management of the elderly, especially elderly patients with chronic diseases, and the transition from public management to personal management are guaranteed to a certain extent. The efficient service quality of the elderly persons and the improvement of the satisfaction and participation of the elderly in medical treatment can stimulate the enthusiasm of the elders to use A.I [1].

Other examples include A.I. based automation in the fields of pathology, hematology, parasitology, and microscopy, as illustrated by the EasyScan_GO microscope, which was developed by Global Good, and launched on the market with the Chinese microscopy company Motic.

Unfortunately, in medicine, a statistical correlation does not always mean that there is a cause and effect relationship. It is important to recognize that much of what we now label as artificial intelligence is in fact statistical intelligence and is, therefore, best applied to problems that can benefit from probabilistic solutions.

It is also important that learning sets of data and truths verified in the field must be carefully developed with clinical

[1] - Xiangfeng ZHANG, Yanmei WANG, Research on intelligent medical Big Data system based on Hadoop and blockchain, journal of wireless communications and networking, 2021, pp 01-21.

validations. Understanding the limitations of the technology is critical to developing useful products, with the appropriate clinical safety profile and predictive value.

Artificial intelligence can help compensate for the lack of the qualified health care personnel. Similarly, in the health field, the developing world severely lacks qualified personnel to meet the society's needs.

According to the British Medical Journal, less than 3% of the world's qualified medical personnel are in the sub-Saharan zone, while 24% of the world's disease cases are in this zone. In South Asia, there are 0.7 doctors per 1,000 inhabitants, and most doctors are found in urban areas. The World Health Organization (W.H.O) estimates that the number of health care workers is seriously insufficient in 57 countries, and that globally there is a shortage of roughly 2.4 million doctors and nurses.

Given the advances in artificial intelligence in the areas of telemedicine, mobile doctors, and virtual classrooms, it stands to reason that artificial intelligence can help solve the problem of the shortage of health workers and thus create an inclusive society[1].

As the appropriation of Artificial Intelligence (A.I) by the D.M industry becomes a reality, it is necessary to look at the applicable regulatory and normative framework. The shift from deterministic software to probabilistic A.I. has put an end to the cards of compliance.

By taking into account mobile applications and cybersecurity, the new MD regulation tackles the technological challenges of the 2000s. The requirements are classic, except for a new classification for software providing information used for diagnostic or therapeutic purposes.

[1] - Stewart UYI, (26-28 November 2018). Artificial intelligence can help bridge the digital divide and create an inclusive society, machine learning for a 5G future. 10th ITU Academic conference. Santa Fe, Argentina.

A framework seems necessary for technical files that will have to define medical intentions, identify the technologies used, demonstrate the proper labeling of data, justify the relevance of learning and test data, or validate the learning cycles.

The information provided to users will be used to document conditions of use, (non)compatibility, and of course the reliability of results. This is an opportunity to clarify that the word intelligence does not change anything: the diagnosis or therapeutic decision will always remain the responsibility of the user. Thus, everything remains to be done for medical A.I.: inventing its applications, generating its uses, identifying its limits, and also managing its lifecycle in order to benefit from its advantages, while controlling its risks[1].

The objective of HDS certification is to organize and supervise the storage and retrieval of health data in conditions that guarantee their confidentiality and security. From a practical point of view, this development should make it possible to improve the timeframe and transparency of the procedures for issuing authorizations, open up the market to international competition and facilitate the change of providers.

This certification is mandatory for any entity that offers a hosting service for personal health data on digital media (apart from electronic archiving services) collected during prevention, diagnosis, care, or social and medico-social monitoring activities, on behalf of health professionals, health establishments, and services and any other organization carrying out the prevention, care, medico-social and social monitoring missions.

This means that, in the health sector, this obligation is imposed when personal health data are stored for patients, or for those responsible for processing personal health data for the purposes of prevention, health care, which includes care and diagnosis, or the social and medico-social care of individuals. In

[1] - Guillaume PROME, Which regulatory/normative framework for a DM integrating AI? DeviceMed,vol 12, January-February, 2019, p. 29.

addition, if the hosting of this type of data is to be entrusted to a third party, it will be necessary to ensure that the hosting provider is HDS-certified[1].

The future of public health is likely to be increasingly digital, and recognizing the importance of digital technology in this field and in pandemic preparedness planning has become urgent. Key stakeholders in the digital field, such as technology companies, should be long-term partners in preparedness rather than being partners when there are solely ongoing emergencies. Viruses know no borders and, increasingly, neither do digital technologies and data. There is an urgent need for alignment of international strategies for the regulation, evaluation and use of digital technologies to strengthen the pandemic management and future preparedness for other infectious diseases[2].

B-Inalienable intervention of intellectual property rights

The coronavirus disease 2019 (COVID-19) pandemic constitutes an extraordinary global public health crisis. It has created a growing pressing need for intensified global cooperation. The pandemic has from its outset raised issues at the crossroads of public health policy, trade policy and the framework for and the management of innovation, including those related to intellectual property (I.P) rights[3].

If the protection of a drug by intellectual property law is indispensable, so that the company that manufactures it can make a profit on research and development costs, it must be reconciled with the protection of public health and, in particular, assist the population gain a wider access to medicines.

---

[1] - Sara SOHIER, The new HDS (Health Data Hosting) certification procedure. DeviceMed, vol 12, January-February , 2019, p. 67.

[2] - Jobie BUDD and others, Digital technologies in the public-health response to COVID-19, Nature Medicine, VOL 26, August 2020, pp 1183–1192

[3] - World Trade Organization, World Health Organization and World Intellectual Property, OrganizationPromoting Access to Medical Technologies and Innovation, Intersections between public health, intellectual property and trade, 2nd Edition, W.I.P.O Publications, 2020

It is worth noting that intellectual property law is an intermediary that makes it possible to regulate these balances. The protection of public health is becoming increasingly important. It is becoming a guideline when concluding international agreements in the medical field. This imperative to protect public health may lead to less favorable conditions for patent holders.

A balance between access to medicines has been established to encourage drug research and development. The agreements on intellectual property rights initiated by the World Trade Organization (W.T.O) take into account the economic level of each member country; this flexibility is the subject of numerous bilateral agreements, which coexist with the trade-related intellectual property rights agreements (T.R.I.P.S) of 1994.

Many problems such as the re-examination or extension of the validity of a patent give rise to increased surveillance and legislation that is difficult to keep up to date. The T.R.I.P.S Agreement recognizes the importance of public health protection and provides flexibility for access to medicines in situations of national emergency. Until the Doha Declaration in 2001, the W.M.C. affirmed the importance of health protection in order to promote access to medicines.

The W.T.O. is well aware that access to medicines is an important aspect of public health. These provisions have been a guideline for member states, which have transposed them into their national laws[1].

Of course, medication is a very important element in public health. The interest in public health protection issues in multilateral agreements has been the result of negotiations between public and private entities. Medicines, therefore, lies at the heart of the relationship between intellectual property protection and access to health products.

[1] - Alain BELTRAN, Patents and trademarks, a history of industrial property. Paris: Fayard, 2001.

On the one hand, patent and trademark law tries to engage exclusive rights of exploitation to guarantee the manufacturer the reimbursement of the sums committed.

On the other hand, public health protection makes attempt to reduce the scope of these exclusive rights to facilitate access to medicines. Intellectual property law creates mechanisms to gain access to medicines: the granting of a patent without the authorization of the patent holder in the compulsory license; the production of the generic drug through the expiration of the patent's validity and repackaging of the brand-name drug package in parallel drug implementations.

The compulsory license is an exceptional use. This mechanism allows access to the drug without the consent of the patent holder. Derogation from the intellectual property right is conditional on the public health is at stake. The conditions are precise but are depend on the level of protection in each country. Each jurisdiction assesses the failure or insufficiency of exploitation of the patent by its beneficiary, which may resemble an anti-competitive practice; this is a proven case of compulsory licensing.

This may also be necessary in the case of refusal to grant the license to others, but especially for reasons of a serious health emergency. The latter case is a solution when a country is faced with a serious contagious disease, a dangerous pandemic affecting a particular geographical area, in which the international community also has a clear interest.

This position can be found in the Algerian legislation, referring to article 49 of ordinance 03-07[1] , which stipulates that :

A compulsory license may be granted at any time by the Minister in charge of industrial property to a State service or to a third party designated by the Minister, for a patent application or for a patent of invention, in one of the following cases:

[1] - Ordinance 03-07 of July 19 ,2003, official journal, n° 44, pp. 23-33.

- When the public interest, in particular, national security, nutrition, health, or the development of other sectors of the national economy requires, and in particular when the fixing of prices for patented pharmaceutical products that are excessive or discriminatory in relation to average market prices ;

- When a judicial or administrative body judges that the manner in which the patent holder or his licensee exploits the invention is anti-competitive and when the minister in charge of the industrial property is convinced that the exploitation of the invention in application of the present paragraph will allow this practice to be remedied.

It is clear that the aforementioned text applies in the case of the COVID 19 coronavirus pandemic, and in the case of a patent for an invention related to a vaccine against this pandemic, the grant of the patent will automatically be closely linked to the compulsory license.

This is due to the free exploitation without the authorization of the holder, as it is a case of a pandemic legally covered by the exception of the compulsory license and justified by the public health interest emanating from public health in such situations.

The position of the Algerian legislator is thus inspired by the T.R.I.P.S agreement, because the already stated article 31 b) of the T.R.I.P.S. agreement sets out the other uses without authorization of the right holder " b) such use may be permitted only if, prior to such use, the candidate user has made efforts to obtain the authorization of the right holder, according to reasonable commercial terms and conditions, and if his efforts have not been successful within a reasonable period of time.

A member may derogate this requirement in situations of national emergency, or other circumstances of extreme urgency, or in cases of public non-commercial use. - In situations of national emergency or other circumstances of extreme urgency, the right holder shall nevertheless be notified as soon as reasonably practicable. - In the case of public non-commercial use, wherein the government or the contracting enterprise,

without conducting a patent search, knows or has demonstrable grounds to know that a valid patent is or will be used by or on behalf of the government, the right holder will be notified promptly.

With reference to a situation of urgency or extreme urgency, the law does not provide specific criteria for determining it; they may be based on state security, protection of the public interest in health or nutrition, protection and improvement of the human environment, or a special interest in a specific branch of the economy, even war or uprising or other similar emergencies, natural disaster, major accident, defense of the nation, emergency or public good for non-commercial purposes, national security, protection of the public interest in health, food supply, protection and improvement of the environment, specific commercial interest.

Other indications are based on public health problems resulting from H.I.V/AIDS, tuberculosis, malaria, and other epidemics that may cause the interruption of normal life and activity of the population, war or any emergency that may possibly threaten the country or any natural disaster or pandemic, serious disease; as exceptions and limitations to patent rights[1].

Compulsory licensing for the export of patented products to countries with no manufacturing capacity has been introduced, based on the Doha Declaration 2001.

Paragraph 6 of the Doha Declaration states that "We recognize that W.T.O Members with insufficient or no manufacturing capacity in the pharmaceutical sector may face difficulties in making effective use of compulsory licensing under the W.T.O Agreement on T.R.I.P.S. We instruct the Council for T.R.I.P.S to find an expeditious solution to this problem and to report to the General Council before the end of 2002.

[1] - Discussed by the Standing Committee on the Law of Patents, Twenty-first Session, Geneva, November 3 - 7, 2014

Finally, it has been asserted that we need to focus on the technologies capable of producing large-scale effects, similar to the effects that technology has been able to bring to high-income countries. Designing inventions that can achieve these effects requires a thorough understanding of the problems before making attempts to solve them with technological solutions.

In this context, the field of engagement is a "reverse innovation", that tends to look at problems from the perspective of people in low-income countries and tries to identify gaps that science and technology can fill.

Success is linked to the resulting inventions that can have an impact on the entire population and act as a catalyst for societal change[1].

Conclusion:

In short, it should be emphasized that intelligent inventions in the field of health represent a priority, following an encouraging and urgent policy linked first and foremost to research and development in Algerian universities and also within the start-ups. The latter being considered as a "motor" of the national economy, and in order to arrive at a viable economic model concerning them, it is a question of moving to the stage of awareness and popularization of the interest emanating from the investment of start-ups in the field of health.

Thus, the following recommendations are suggested:

- Adopt an "Intelligent Health Innovation Pact" that will guarantee our country's leadership in the field.

- Take advantage of intelligent inventions in the field of health in an equitable manner, in order to meet the conditions of sustainable development, especially the patient in this kind of situation is autonomous, but remember that this autonomy requires in any case the restoration of the sense of touch.

[1] - Michael VECCHIONE, op.cit.

-The popularization of the provisions related to patents for intelligent inventions linked to health, and in particular the provisions associated with compulsory licensing. The current difficult period that the country and the other countries go through, necessitates moving to a legal control over the exploitation of health inventions, mainly the urgent and urgently needed exploitation of vaccines against the Corona Virus COVID 19.

Bibliography :

A - Books:

-BELTRAN Alain, Patents and trademarks, a history of industrial property. Paris: Fayard, 2001.

-SOUDOPLATOFF Serge, Artificial intelligence: expertise everywhere accessible to all. Foundation for Political Innovation editions, FEBRUARY 2018

-VILLANI Cedric, Health and Artificial Intelligence, National Health Insurance Plan Information System. Paris: NRC, 2018.

B - Journal Articles:

-BENASSI Mario , GRINZA Elena , RENTOCCHINI Francesco , The rush for patents in the Fourth Industrial Revolution, Journal of Industrial and Business Economics, May 2020, pp 01-30.

-BESSE Philippe, Legal and ethical implications of artificial intelligence algorithms in health care. hal-02424285v2, March, 2020, p. 09.

-BOHR Adam, MEMARZADEH Kaveh, The rise of artificial intelligence in healthcare applications, Artificial Intelligence in Healthcare, 2020, pp 25-58.

-BUDD Jobie and others, Digital technologies in the public-health response to COVID-19, Nature Medicine, VOL 26, August 2020, pp 1183–1192.

-BUZYN Agnes, Innovation at the service of our health care system. Voices of research, December 2018,pp02.

-DENIEL Philippe, Protecting health data, Ensuring the best protection. Voices of Research, December, 2018, p. 43.

-DIMITROV Dimiter, Medical Internet of Things and Big Data in Healthcare. Health Inform Res, n°63, 2016, p. 156.

-FIORINI Marco, Artificial intelligence, innovative vectors, health2030, Leem, 2019, p. 45.
-KHAN Faizal, ALOTAIBI Sultan Refa, Applications of Artificial Intelligence and Big Data Analytics in m-Health: A Healthcare System Perspective, Journal of Healthcare Engineering, 2020, pp 01-15.
-LACHERE Julien, Trends in investment and patents in the field of artificial intelligence, Strategic file, Innovating to survive: are you a precursor or a follower? BCA, October, 2019.
-LACHERE Julien, Trends in investment and patents in the field of artificial intelligence, Strategic file, Innovating to survive: are you a precursor or a follower? BCA, October 2019.
-MAISNIER-BOCHE Laurraine, Artificial intelligence and health data. Journal of Health and Deseases Insurance Law, Number 17 – 2017,p. 25.
-Mc Kinsey and company, Transforming healthcare with AI. The impact on the workforce and organisations, European Union, March 2020.
-PROME Guillaume , Which regulatory/normative framework for a DM integrating A.I? DeviceMed,vol 12, January-February, 2019, p. 29.
-RAZA ABIDI Syed Sibte, RAZA ABIDI Samina, Intelligent health data analytics: A convergence of artificial intelligence and big data, Healthcare management forum, 2019, pp 01-05.
-SOHIER Sara,The new HDS (Health Data Hosting) certification procedure. DeviceMed, vol 12, January-February , 2019, p. 67.
-ZHANG Xiangfeng, WANG Yanmei, Research on intelligent medical big data system based on Hadoop and blockchain, journal of wireless communications and networking, 2021, pp 01-21.

C - Seminar articles:

-GUJRAL Garima, Artificial intelligence (A.I) and data science for developing intelligent health informatics systems, National Conference on AI in HI & VR, SHSS-TISS Mumbai, August 30-31, 2019.

- UYI Stewart, Artificial intelligence can help bridge the digital divide and create an inclusive society, machine learning for a 5G future. 10th ITU Academic conference. 26-28 November 2018Santa Fe, Argentina.
-VECCHIONE Michael, Technologies for social good - an innovative approach, machine learning for a 5G future. 10th ITU Academic conference, 26-28 November 2018, Santa Fe , Argentina.