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A Portuguese and European perspective on telemedicine and e-health

Launch interactive document

Ricardo Costa Macedo and Diana Mâncio da Costa, of Caiado Guerreiro, Sociedade de Advogados, discuss the needed reinvention of medical care and how it is redefining the relationship between healthcare services providers and patients.

CTC Legal Media

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Editor's welcome

In the world we currently find ourselves in, it is no surprise that there has been an increased urgency for telemedicine and e-health. Experts from Caiado Guerreiro, Sociedade de Advogados, discuss, in our cover story, the need for the reinvention of medical care. This conversation explores a Portuguese and EU perspective on what telemedicine means for health care, including technological developments, patient information, and the relationship between health service and patient.

> "Increased urgency for telemedicine and e-health."

Developing further from this conversation, we look at health data and its transfer, sharing and usage – this time from a UK perspective from Baker McKenzie. In light of both Brexit and the NHS information governance, this article discusses the partnership between the NHS and the private sector, the national opt-out deadline, and the code of practise for record management.

Then, a look to AI and the types of protection available for related inventions. This article provides an overview of the fields of application, the regulatory challenges one may face, and a comparative approach to available protection pathways.

LexOrbis offer an informative discussion on functional claiming, looking to both the USPTO, EPC, and EPO for guidance and examples, and explain what this can offer to life sciences inventions in the field in the Indian legal system.

Enjoy the issue.

Faye Waters

Faye Waters
Editor

Mission statement

The *Life Sciences Lawyer* educates and informs professionals working in the industry by disseminating and expanding knowledge globally. It features articles written by people at the top of their fields of expertise, which contain not just the facts but analysis and opinion. Important judgments are examined in case studies and topical issues are reviewed in longer feature articles.

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A Portuguese and European perspective on telemedicine and e-health

Ricardo Costa Macedo and Diana Mâncio da Costa, of Caiado Guerreiro, Sociedade de Advogados, discuss the needed reinvention of medical care and how it is redefining the relationship between healthcare services providers and patients.

In the context of the COVID-19 pandemic and the numerous problems that came with it, outpatient visits had to be cancelled and patients faced the fear of visiting hospitals and physicians' practices. Medical care simply had to be reinvented; technology and already in motion programs for e-health proved to be a true ally of healthcare systems all over the world.

In fact, technology has been an essential part of the strategy adopted to face the challenges posed by this pandemic, especially at a time when national health systems are facing real difficulties in providing healthcare services to their citizens.

Although telemedicine and e-health are not new concepts, a new wave has brought them to the epicentre of the debate, being that the effects of the recent urge to use them are here to stay.

Ricardo Costa Macedo

Diana Mâncio da Costa

The concepts of E-Health and Telemedicine

E-Health may be defined as the use of information and communication technologies (ICT) for health, and telemedicine as the provision of healthcare services where traditional face-to-face patient - doctor interaction is replaced by over distance interaction through use of ICT.

E-health and telemedicine are having an undeniable impact on healthcare. As it is expected, the technologic developments the world has been witnessing are also widespread to the medical area, not only to the realm of medical devices but also in the way patients and doctors interact.

Such technological advances however are not necessarily being followed by the development of an adequate regulatory framework. The legislation surrounding telemedicine is actually quite delayed, as countries have only issued general recommendations, as it is the case of the EU with the publication of the Green Paper on Mobile Health.

Telemedicine services form a rather complex web, where multiple aspects are interconnected, from patients' sensitive data to reimbursement. Consequently, it is hard for national legislators to draw up a general framework that will encompass the numerous factors emerging from the use of telemedicine services.

Notes on the EU perspective on telemedicine

For the last decades, the European Union has been perceiving e-health and telemedicine as steps towards better quality of healthcare.

The EU has shown great interest in the development of e-health platforms, as these may serve to alleviate the heavy financial burden of public health systems, to stimulate the economic development of the EU regions (due to the technological innovation) and to allow for an easier access to cross-border medical assistance by EU citizens.

Article 14 (1), on "eHealth", of the Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011, establishes the need for the support, cooperation, and exchange of information among Member States working within a voluntary network, with the goal of connecting national authorities responsible for eHealth designated by the Member States. Said Directive, concerning the application of patients' rights in cross-border healthcare, is considered relevant for the regulatory framework of e-health provided by the EU.

Moreover, the Directive establishes objectives for said eHeath network, such as the preparation of guidelines on different matters and the need for the support to Member States in the development of measures that will facilitate transferability of data in cross-border health.

Nonetheless, when addressing e-health services at an EU level, there are other significant legal instruments that should be taken in consideration, such as the EU legislation on Data Protection, E-commerce, Medical Devices, Consumers' Rights and Electronic Identification and Security of Network and Information Systems.

A coherent set of rules to govern telemedicine and e-health services in all EU Member States

Résumés

Ricardo Costa Macedo, Lawyer and Partner at Caiado Guerreiro, Head of Intellectual Property and Life Sciences groups

Mr. Macedo's practice covers a wide range of contentious and non-contentious patent, trademark and other Intellectual Property related rights, such as trade secrets and unfair competition, in particular in the pharmaceutical, home care, food and insurance sectors.

Mr. Macedo graduated from the Faculty of Law of the Catholic University of Lisbon, in 1998. He undertook postgraduate studies in Information Society Law, at the Faculty of Law of the University of Lisbon, in 2000, and in Commercial Law, at the College of Law, London, in 2003.

Diana Mâncio da Costa, Junior Lawyer at Caiado Guerreiro

Ms. Diana Mâncio da Costa has been collaborating with Caiado Guerreiro since 2018 and is a member of the Intellectual Property and Life Sciences groups. Ms. Costa has been focusing her practice on the pharmaceutical and health sectors, in relation to which she covers a wide range of matters.

Ms. Costa graduated from the Faculty of Law of the Catholic University of Oporto, in 2017, and concluded her Masters of Laws (L.L.M.) in Globalisation and Law – Commercial and Corporate Law at the Faculty of Law of the University of Maastricht, in 2018.

may be hard to accomplish. In any case, and even though the development of eHealth solutions is a matter undertaken internally by Member States, the EU has been committed to providing funding and platforms for the collaboration of EU members on this matter.

An example of the enhancement of said collaboration is the "eHealth Digital Service Infrastructure" that is introducing two electronic cross-border health services in all EU countries: the ePrescription and the Patients Summaries, both of which are already available in Portugal.

More recently, Commission Implementing Decision (EU) 2020/1023 of 15 July 2020 regarding the cross-border exchange of data between national contact tracing and warning mobile applications with regard to combatting the COVID-19 pandemic was published. This may be perceived as a sign that the EU is interested in proposing the needed regulation for healthcare applications and in tackling the problems, for instance related with data protection, that said services may pose.

> **"The EU has been committed to providing funding and platforms."**

Portugal: Embracing Telemedicine

Well before the current COVID-19 pandemic came about, ambitious programs were already being put in place in Portugal, aiming at expanding the use of electronic means for the rendering of healthcare services.

Since the 90's, Portugal has been developing a revolutionary approach to e-health, with the latest development being the launch of PENTS in 2019.

PENTS is the National Strategic Plan for e-Health. Its goal is to set a strategy for the enhancement of technologic and electronic health care in Portugal. This innovative program regards e-health as an opportunity to respond to the challenges posed by a society that is gradually aging.

PENTS is also a solution for the problems generated by the geographical isolation of some locations in Portugal and the difficult access to healthcare, also allowing for the remote group collaboration of various professionals.

In regard to the legislative framework for telemedicine in Portugal, it should be noted that already in 2013, Dispatch No. 3571/2013, of 6 March, was published. Said Dispatch determined that the services and establishments of the National Health Service (NHS) should intensify the use of information and communication technologies to promote and guarantee the provision of telemedicine services to NHS users.

Subsequently, and with the intent of reinforcing the implementation of the strategy for a Telemedicine Network in the National Health Service (NHS), Dispatch No. 8445/2014, of 30 June, was published. In said Dispatch, it was established the need for the general access to telemedicine, considering the technologic capacities of the institutions and the aim of increasing the accessibility to medical care and maximizing the installed capacity of the institutions of the NHS.

Lastly, it should be noted that the Regulation of Medical Ethics (Regulation 707/2016, of 21 July) extensively regulates the use of telemedicine services.

In accordance with the Portuguese Medical Association, there are some aspects that should be kept in mind when considering telemedicine services, such as the respect for the patient-doctor relationship, the independence of the doctor's opinion and the confidentiality and mutual confidence.

Particular attention should be paid to the fact that the regulatory framework provided by said Medical Association only appears to allow the use of e-health services when the conditions are similar to the ones of a face-to-face consultation and when the doctor has sufficient knowledge of the clinical situation of the patient. Moreover, physicians should only use telemedicine services after they ensure that the system used and its users guarantee the medical secrecy, namely through the encryption of names and other identifying data.

Closing notes

Although telemedicine is not new, it seems that its potential to facilitate the contact between patients and doctors had not been fully recognized until the COVID-19 pandemic started.

Even if telemedicine should not replace the so-called standard medicine, nor overrule the need of a personal contact between doctor and patient, it remains that by allowing the practice of medical acts and health procedures from a distance telemedicine is helping countries battling some of the biggest problems in the health sector such as the ageing population or difficult access to medical care in some regions.

From an EU regulatory perspective, the use of e-health services is regarded as generally regulated in legal instruments already available, as is the case of the EU legislation on Data Protection and on Medical Devices.

In this sense, although there is no specific legislation for e-health in the EU, it could be argued that there is already a set of rules that will play a relevant role in designing a future general framework for the use of e-health services and that the same already provides guidance for those dealing with e-health services and its applications.

> **"It is hard to conceive the future of medical care without these services."**

Notwithstanding, there is room to say that the EU current regulatory framework is still insufficient to regulate, in a detailed and coherent manner, the phenomenon of e-health and telemedicine.

Such regulation may be hard to conceive not only because EU Member-States retain internal relevant competences in matters related to healthcare but also because some topics, such as medical liability, may prove difficult to address.

As for the Portuguese scenario, and even before the pandemic stroke, there were already signs of investment in large programs that will enhance the use of telemedicine in the country, the PENTS program being one of them.

In addition, legislation has already been enacted to promote the use of telemedicine and the Portuguese Medical Association has specific guidelines for the use of telemedicine services.

What the future holds for e-health and telemedicine is still unknown, and even though the recent changes in the intense use of e-health services were not based on a choice of doctors and patients, but instead imposed by the COVID-19 pandemic, it is hard to conceive the future of medical care without these services.

E-health and telemedicine will require us to redefine the relationship between healthcare services providers and patients, setting a new measure for the protection of patients' rights and public health information systems and potentially even addressing medical liability and other issues that may emerge within an international environment of provision of medical care.

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Health data in the UK: What's next for 2021?

Jaspreet Takhar, Senior Associate at Baker McKenzie, suggests what Brexit and NHS information governance will mean for data transfers, sharing, and use in 2021.

2020 was a big year for health data in the UK. In the year of Brexit and COVID-19, information governance was key. So what does 2021 have in store? We anticipate a final decision on the status of transfers of personal data from the EEA to the UK, post-Brexit. Data sharing collaborations between the private and public sector will continue to be a hot topic. Finally, NHSX will continue to enhance NHS information governance requirements, including the National Data Opt-Out and records management guidance.

Health data in 2020

2020 saw some key developments for health data in the UK. With the Brexit transition period now over, organisations must comply with the GDPR as it is incorporated into national law (UK GDPR). Towards the end of 2020, NHSX also launched a brand new information governance portal, providing a 'one-stop shop' for NHS policies and guidance.[1] NHS supplemental laws and guidance have traditionally been difficult to navigate, so this is welcome news for NHS suppliers and collaborators. Finally, there was a renewed focus on medical confidentiality, and the National Data Guardian made some updates to the Caldicott Principles.

Jaspreet Takhar

> "Data sharing between the private and public sector will be a hot topic."

Résumé

Jaspreet Takhar, Senior Associate

Jaspreet advises market-leading tech and healthcare companies on issues at the cutting-edge of digital health. She focuses on the development and regulation of healthcare technology. This includes assessing how digital health solutions can comply with the legal framework for data privacy, medical research and medical devices / pharmaceuticals. Jaspreet also advises clients on accessing and using patient data, innovative collaborations with hospitals, and the use and regulation of AI in the healthcare space.

5 topics on the horizon for 2021

1. Partnerships between the NHS and the private sector

We have seen an explosion in the number of collaborations between the NHS and the private sector in recent years. The private sector is increasingly accessing and using datasets from various NHS organisations to develop data-driven healthcare technology. These partnerships continue to come under the spot-light of media and government. Commentators are scrutinising compliance with data privacy and the common law duty of confidentiality. NHS organisations are increasingly asking, what is in it for the public sector in these deals?

2020 saw NHSX publish a Data Sharing Agreement (DSA) template.[2] The DSA template is a useful tool for companies collaborating with NHS organisations to access and use data (as well as for a host of other purposes). The DSA encourages the relevant NHS organisation and its counter-party to consider key risks related to data privacy and medical confidentiality. Crucially, the parties will need to set out the basis on which personal data (and any special categories of data, such as health data) are shared under both the GDPR and the common law duty of confidentiality.

These partnerships will continue to be an area of focus for the NHS in 2021. We expect organisations such as NHSX will continue to issue guidance focussing on demonstrating compliance and value for the NHS in these partnerships.

2. Anonymisation and the (messy) intersection of data privacy and the common law duty of confidentiality

NHSX's Health and Care Information Governance Panel (Panel) informs NHS priorities for new information governance guidance. In their last meeting of 2020, the Panel highlighted pseudonymisation as an area of focus.[3]

Once data is truly anonymised, it will not fall within the scope of the GDPR and it becomes easier to use. However, anonymisation under the GDPR is a high bar and very difficult to achieve in practice. It involves removing personal identifiers, both direct and indirect, that may lead to an individual being identified. This is more stringent than the traditional understanding of 'anonymisation' under the common law duty of confidentiality as it applies in the healthcare sector.

Often, data considered 'anonymised' for confidentiality purposes is actually 'pseudonymised' data for GDPR purposes. Pseudonymised data may include data where key identifiers have been removed and the data can no longer be attributed to a specific individual without the use of additional information (and such additional information is kept separately and subject to certain technical and organisational measures to ensure non-attribution to an individual). The key takeaway is that pseudonymised data is still personal data subject to the GDPR.

The Panel appears to have picked up on this discrepancy on the thresholds for anonymisation under the GDPR and the common law duty of confidentiality. The minutes[4] of the last Panel meeting identifies *"the issue around how the health and care sector would handle pseudonymised data - if it should be treated as confidential patient information and what safeguards are required to ensure pseudonymised data is not re-identified."*[5] A dedicated working group is being set up to discuss this, so watch this space for further developments.

3. National data opt-out deadline: 31 March 2021

The national data opt-out[6] is a service allowing NHS patients to opt out of their confidential patient information being used for research and planning. The information includes that collected in the course of publicly funded, commissioned or coordinated health and adult social care, as well as private care given in NHS settings. The national data opt-out does not apply where data is shared for a patient's care.

All health and care organisations that process health and social care information as a controller must be compliant with the national opt-out policy by 31 March 2021.

The original deadline had been extended to enable health and care organisations to focus their resources on the COVID-19 outbreak. In-scope organisations must ensure there are systems in place to facilitate a patient's opt-out and processes to ensure that patient's data is not used for research and planning purposes.

> "Once data is truly anonymized, it will not fall within the scope of the GDPR."

4. Brexit and EEA to UK transfers of personal data

EEA to UK data transfers: On Christmas Eve the UK and the EU concluded a Trade and Cooperation Agreement (Agreement) in principle, and there was one Christmas present for data protection lawyers: the transfer of personal data from the EEA to the UK may continue without safeguards (e.g. standard contractual clauses) from 1 January 2021 for a period of four months. This period will be automatically extended by a further two months if neither the UK nor the EU objects. This is on the condition that the UK continues to apply the UK GDPR. The period will end earlier if the European Commission adopts an adequacy decision in relation to the UK.

UK to EEA data transfers: The Agreement did not address transfers of personal data from the UK to the EEA, but these transfers can also continue without safeguards after the transition period because the UK has already designated EEA member states as providing an adequate level of protection of personal data for the purposes of the UK GDPR. This designation can be withdrawn at any time.

5. New Records Management Code of Practice

The Records Management Code of Practice (2016) (Code) sets out what people working with or in NHS organisations in England must do to correctly manage records. The Code focuses on how long records should be retained by an organisation in possession of NHS data. It is based on the legal requirements and professional best practice published by the Information Governance Alliance in 2016.

Despite only being a few years old, the Code is already out-of-date (it pre-dates the GDPR). A consultation for a new Records Management Code of Practice 2020 recently concluded, so a new version is in the works.[8] The revised version of the code will be published once NHSX have analysed the responses and updated the code. The 2016 version is still valid until the new code has been finalised.

1 https://www.nhsx.nhs.uk/information-governance/guidance/
2 https://www.nhsx.nhs.uk/information-governance/guidance/data-sharing-agreement-template/?utm_source=twitter&utm_medium=social&utm_campaign=ig_staff
3 https://www.nhsx.nhs.uk/information-governance/health-and-care-information-governance-panel/minutes/2020-09-15/
4 https://www.nhsx.nhs.uk/information-governance/health-and-care-information-governance-panel/minutes/2020-09-15/
5 https://www.nhsx.nhs.uk/information-governance/health-and-care-information-governance-panel/minutes/2020-09-15/
6 https://digital.nhs.uk/services/national-data-opt-out
7 https://ec.europa.eu/transparency/regdoc/rep/1/2020/EN/COM-2020-857-F1-EN-ANNEX-1-PART-1.PDF
8 https://www.nhsx.nhs.uk/information-governance/guidance/records-management-code/

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The use of Artificial Intelligence in life sciences and the protection of IP rights

Janett Lumbreras, Senior Associate, Uhthoff, Gomez Vega & Uhthoff S.C, discusses types of protection available for protecting AI innovations in the field with an explanation and a for and against approach.

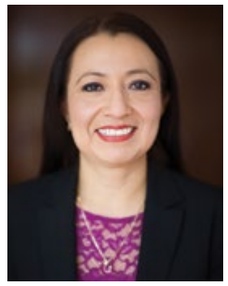
Artificial Intelligence (AI) is transforming the life-sciences industry by making discoveries from massive biological data using machine learning, integrating clinical records and genomic data of different kinds, discovering new medicine or drug targets, identifying new classes of cell types, carrying out diagnostics, or customizing clinical procedures in precision medicine.

Artificial Intelligence involves a number of different technologies, primarily machine learning, deep learning, neural networks, natural language processing, and computer vision. There is a considerable degree of connection among them, but the core technology is machine learning. So, bearing in mind that this technology could fall in the exception of patentability under some legislation, it is necessary to consider new regulations to protect the IP rights. Thus, several aspects should be considered when protecting this technology and choosing how to protect it.

Fields of applications in life sciences

Before continuing, it is important to briefly explain what Artificial Intelligence is. It is defined as *computer systems able to perform tasks normally requiring human intelligence such as visual perception, speech recognition, **decision-making**, and translation between languages.*

Artificial Intelligence originates from computer science and covers a wide range of approaches intended to enhance the ability of machines to make data-driven decisions and accurate predictions of events. In many scientific fields, AI is being increasingly considered and integrated, especially in the context of Big Data. Given their complexity and highly interdisciplinary nature, life sciences provide ample opportunities for AI to impact R&D efforts in a variety of ways.


Janett Lumbreras

> "Visual perception, speech recognition, decision-making, and translation between languages."

There are numerous areas where the life-science industry uses AI effectively today. Some of them are the following:

- **Pharmaceutical research, pharmacology, and drug discovery.**
- **Accelerating drug development:**

Scientists are integrating research data, lab data, and clinical data, in combination with new information sources (e.g., social media and wearables) across the drug development spectrum, creating a holistic picture of the drug development candidate. Improving ways to acquire and mine data in real time allows

Résumé
Janett Lumbreras - Senior Associate
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scientists to use AI and machine learning to make better decisions faster, which will accelerate the product development and scale-up process.

- **Epidemiology and clinical investigations.**
- **In silico modeling and simulation of molecular systems and organisms.**
- **Designing clinical trials:**

Artificial Intelligence can design clinical trials, estimating the ideal sample size, and implementing them remotely on participants across a wider geographical area. This, in turn, reduces the cost and increases the odds of obtaining relevant and accurate data.

- **Introducing robotic surgery:**

A new field that is garnering a considerable amount of interest. Nowadays, surgeries can be performed in previously inaccessible places. Once trained, a robot will be competent enough to perform each operation consistently and accurately. The consistency and accuracy of the surgery will be irrespective of the duration of the surgery. It is touted to be superior when compared to human performance, which will predictably decline with time.

- **Developing the next-generation of radiology tools:**

The current diagnostics processes rely on either invasive techniques or information gathered from radiological images. This includes data from CT scans, X-rays, or MRI machines. AI-based radiology tools will enable clinicians to gain a more precise and detailed understanding of how a disease progresses by performing virtual biopsies.

- **Telemedicine:**

Unavailability or dearth of trained professionals such as radiologists or ultrasound technicians can considerably limit access to life-saving care. This is commonly observed in emergent and developing parts of the world. The AI-powered tool "Telemedicine," which equips patients to tackle and prevent certain health concerns, has become popular in such regions. The health care start-up "WeDoctor" can independently conduct eleven diagnostic tests and upload data for consultation in an automated fashion.

- **Clinical Trials:**

Clinical Internet of Things refers to the ability of patients to wear mobile devices and sensors that will capture and provide a stream of quality, nearly real-time data to researchers. AI is the technology those researchers will use to analyze the data and look for information, insights, or patterns. It has been defined as machines being able to perform "smart" tasks that are characteristic of human intelligence.

> "Then the value of patenting that invention is diminished."

Machine learning is a term that refers to the ability of AI algorithms to learn and develop without being explicitly programmed.

Life sciences companies are likely to begin experimenting further with AI in their workflows in the coming years, but they face challenges in AI adoption due to strict regulations.

The regulatory challenge

Artificial Intelligence and Machine Learning (AI/ML) involves new computing technologies, and vast amounts of training data that pose new regulatory challenges such as:

- Determining the accountability for providers of AI/ML-based solutions and assigning liability for harm caused by the "black box" of an AI/ML process.
- Assuring the quality and safety of products or therapies developed using AI/ML.
- Guaranteeing that the data and/or algorithms used in AI/ML solutions are not biased against underserved populations.
- Ensuring that the AI/ML solutions developed are sustainable and environmentally friendly, and that the recommendations are not in conflict with societal priorities such as social justice.
- Protecting the privacy of patients and their data. Existing patient privacy rules do not, for example, protect patient data when it is shared and used by technical or consumer marketing organizations rather than healthcare providers.

Thus, international and national legislations must be adapted or must be created to regulate the safe use and protection of the AI-related IP rights.

Protection of Artificial Intelligence innovations in life sciences

A substantial investment in building and deploying machine learning (ML) technology – the most active area of AI technology being developed today – warrants carefully considering how to protect the resulting intellectual property rights, but there are challenges in doing so. Several aspects should be considered when protecting this technology and choosing how it is to be protected, which would be with a patent or with trade secret protection.

Trade Secret protection

Protecting by Trade Secret, there is no time limit on trade secret protection so long as the subject matter is kept secret, and there are no eligibility, novelty, or obviousness bars to clear. There is, however, no recourse for independent discovery by a competitor. Important factors to consider when weighing trade secret and patent protection include:

1. Detectability. If detecting when a competitor uses an invention is hard, then the value of patenting that invention is diminished because it will be difficult to know that the patent is being infringed. This may be the case with innovative training algorithms for ML systems—it is perhaps possible to detect that the ML system is being used, but hard to detect how it was trained. This might suggest the trade secret route for such technology.

2. Reverse Engineering. If it is easy to reverse engineer the invention or hard to keep it secret (e.g., due to desire to publish or visibility of the invention in the product), then the patent route may be preferable.

Trade secrets offer a degree of protection in circumstances where patenting is not the best approach.

Keeping part of an invention secret is an option if:

- time is needed to generate more experimental data to ensure optimal scope of protection.
- the invention could not be described in a reproducible way without disclosing training data that should remain secret.
- patent case law is not favorable in terms of patent eligibility.

> "There is a possibility that it is harder to gain patent protection for individual new drugs found using the AI algorithm."

- infringement is hard to detect.
- the lifecycle of the invention is short.
- the filing behavior of the competition is not active.

Trade secret protection can be very cost-effective since there are no official fees to pay. However, there are management and administrative costs to businesses since comprehensive policies and procedures are needed to track and secure trade secrets.

Trade secrets offer a degree of protection in circumstances where patenting is not the best approach.

If the technology needs to be known by several entities, such as software contractors, customers, and a large number of employees, then it may not be practical to be kept secret and trade secret protection is not suitable.

Protection by Patent

These inventions must comply also with the requirements of novelty, inventive step, and industrial applicability to be patented. If claims relate to a method involving the use of technical means, for instance a computer or a device, the subject matter in its entirety is of a technical nature and is patentable as an invention. The question, then, is whether the invention satisfies

other requirements of patentability, in particular novelty and inventive step.

The evaluation of the inventive step, widely considered the more problematic requirement, assesses whether the mathematical method contributes to producing a technical effect that serves a technical purpose. For example, an X-ray apparatus providing a genotype estimate based on an analysis of DNA samples or an automated system providing a medical diagnosis by processing physiological measurements.

Some examples of potentially patentable aspects of an ML system are:

- New ML model: in deploying ML technology, a new model may have been developed (e.g., new neural network architecture). Claiming novel aspects of the model will help to address novelty and inventive step challenges.
- Training an ML model: innovative ways of generating training data and/or a new training algorithm may be claimed. For example, when there is insufficient training data, it may be augmented by synthesizing new training data from old training data or other sources, and such data augmentation techniques may be innovative and, thus, the focus of patent claims.
- Organizing an ML model: how an ML model is integrated into an application may provide a novelty and inventive step hook. Claims focusing on integration and deployment should go beyond merely displaying the model's output and focus on what the output is used to achieve. For example, applying an ML system to medical images may result in instructions to take more images with different settings because the ones obtained are unsatisfactory. Other examples include choosing among different next steps in a control system, customizing a patient's treatment, or updating a clinical trial. When an ML system is deployed in conjunction with a specialized device (e.g., an imaging device, a sequencing device), rather than merely a computer, claims could focus on how the ML system is integrated with the device.
- By publishing a patent application about an AI algorithm for finding new drugs, there is a possibility that it is harder to gain patent protection for individual new drugs found using the AI algorithm. This is because the new drugs are arguably obvious since the AI algorithm is known.

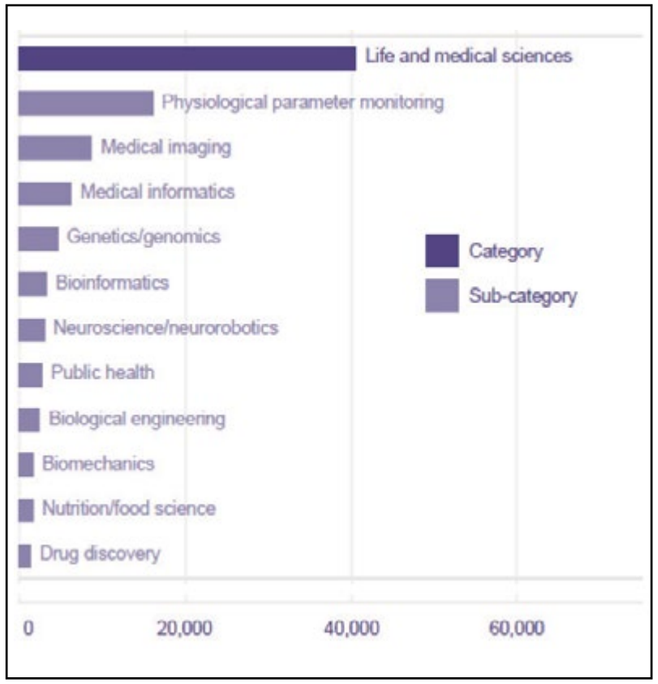
Filing of AI Patent applications

The number of AI-based patent filings has increased rapidly in recent years, particularly in the United States and Asia. Even in Europe, patent filings grew at an annualized rate of over 50% from 2014 to 2017.

Machine learning is the dominant AI technique disclosed in patents. Nevertheless, according to the field of application the main fields are the following:

- Transportation industries (15 percent of all AI-related patents),
- Telecommunications (15 percent),
- **Life and medical sciences (**12 percent).
- Transportation, agriculture, and computing in government are growing industries, with annual growth rates of at least 30 percent between 2013 and 2016.

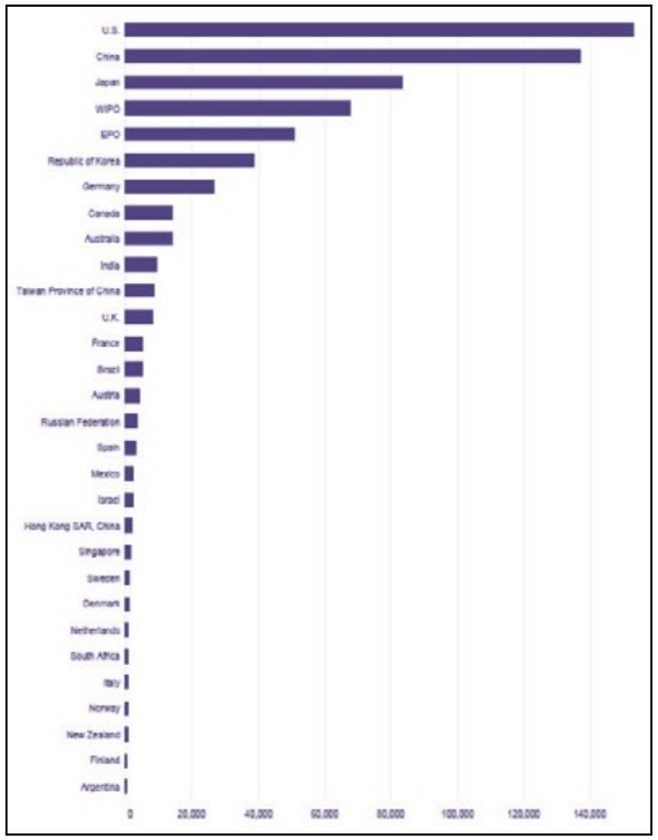
Patent families for application field categories and sub-categories



> **IP policies and practices will interact with the strategy of managing innovation in AI.**

Overall number of patent applications by Patent Office

The greatest number of patent applications are filed in the patent offices of U.S. and China, followed by Japan, while WIPO and the EPO are also often used.



Conclusions

AI is expected to revolutionize processes across a wide range of fields. It is foreseen that AI will also affect intellectual property rights, in particular patent rights and their management. This is likely to be a two-way process: on the one hand, AI developments will affect and be incorporated into IP rights management; on the other hand, IP policies and practices will interact with the strategy of managing innovation in AI.

In addition, as AI develops, some of the questions that are currently discussed only hypothetically may become real issues. These include the inventorship of AI, patent- and more generally IP-rights infringement by AI. Such questions may call for related regulation or a certain interpretation of existing regulations to cover possible gaps and answer related questions.

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AI IPR IN LIFE SCIENCES

Functional claiming in life science inventions in India

Manisha Singh & Pradeep Kumar Kamal, of LexOrbis, look to the USPTO, EPC, and EPO for examples and guidelines of the use of functional claiming to offer guidance for its use in India where the practice is still unsettled.

Structuring of claims which constitute a legal text, defining the scope of an invention of a patent application, is of paramount importance in protecting inventions. Claims crafted narrowly unnecessarily limit the protection, and result in infringers overcoming infringement by showing trivial variations. In contrast, broad claiming, defining a scope which is beyond what is encompassed by the disclosure, runs the risk of invalidation.

> **Runs the risk of invalidation.**

'Functional claiming' is one such way of drafting claims with a much wider coverage with respect to structural components. The expression "functional claiming" refers to define the claims of an invention in terms of functional limitations of the structural component, rather than defining the structural component itself. Use of functional claiming is not confined to any particular field of invention but is associated with almost every field of invention in conjugation with its related terminology. Depending on the technology and the specific invention, functional claiming may be preferable and even unavoidable. At times, an invention (e.g., one software based) may be inherently functional or at least functional at the point of novelty.[1] Functional claiming, in one of its forms, is known to define inventions as a 'means for' performing a function, wherein expression "means for" refers to any broader generic representation of the structural element by using expressions viz. 'means for', 'mechanism for', 'component for', 'apparatus for', 'system for', 'member for', 'compound for', 'agonist for', 'antibodies for', 'probe for' etc. Such means plus function claims thus encompass a range of structural components that can perform the referred function. In life science related inventions, these structural components may be compound, active, biomolecule, nucleic acid, polypeptide, protein, cell lines, etc.

Functional claiming has always remained a dynamic concern among the different patent jurisdictions. While many of the patent jurisdictions recognize that there may be situations where an invention may be defined in functional terms, there is divergent jurisprudence for acceptance of such claims among different patent jurisdictions. While there have been plenty of insightful judicial precedents dealing with functional claiming in United States and Europe, which provide guidance on enablement and indefiniteness issues of functional claims, pockets of grey area remain - which is inherent to dynamism new technologies and associated functional claiming.

The present practice of USPTO to consider and evaluate functional limitation, just like any other limitation of the claim, is the outcome of jurisprudence developed over more than 150 years. US Supreme Court in *O'Reilly v. Morse* (1854) invalidated a portion of Morse's primary patent for being defined as an effect produced by the use of electromagnetism distinct, from the process or machinery necessary to produce it.[2] In 1938, the US Supreme Court invalidated a patent in *General Electric Co v Wabash Appliance Corporation* because it claimed a tungsten filament in terms of its performance rather than its physical characteristics and did not adequately define the structural characteristics of the grains.[3] The US Supreme Court in *Halliburton Oil Well Cementing Co. v. Walker* (1946) held that it is impermissible to use "conveniently functional language at the exact point of novelty".[4] Post *Halliburton* case the U.S. patent statute was amended in 1952 by enacting § 112(f) to authorize means-plus-function claiming. The only suggested requirement that needs to be taken care in functional claiming is that the structure for performing the claimed function must be described in the patent's specification. Federal Circuit in *Williamson v. Citrix Online* case further guided for wider amplitude of functional claiming, by considering non-means claims as means-plus-function claims.[5] However, claim reciting only function as the limitation to its scope without describing in the specification the corresponding structure for performing the recited function are often considered invalid being indefinite.[6]

European Patent Convention (EPC) on the other side stipulates that the claims should define the matter for which protection is sought in terms of technical features, and does not provide any specific provision for facilitating functional claiming.[7] However, EPO, in its Guidelines for Examination, permit inclusion of functional features in a claim, provided that a skilled person would have no difficulty in providing some means of performing said function without exercising inventive skill. The approach of EPO is rather more flexible and lenient one as compared to USPTO.[8] EPO specifically considers one subset of functional claiming to be acceptable upon satisfaction of certain prerequisite. Claims only defined in terms of a 'result to be achieved' are accepted, contingent to satisfaction of conditions that it is not possible to formulate the claim more precisely without unduly restricting the scope of the claims and that it is possible for the skilled person to verify the result without undue burden.[9]

Indian patent law and practice on functional claiming is an unsettled one with no jurisprudence. While there is no statutory bar on claims with functional language, claims with only functional limitations are outrightly considered to lack technical features by Controllers/Examiners of Indian Patent Office. This approach may be connected to existing legal sources *viz.* The Patents Act, 1970 (as amended), Manual of Patent Office Practice and Procedure, different Guidelines for Examination of Patent Applications and judicial precedents, all of which either fail to recognize functional claiming or provide leeway. The statutory definition of invention provided under Section 2(1)(j) of the Patents Act, 1970 (as amended) "'invention' means a new product or

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Résumés

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2. *O'Reilly v. Morse*, 56 U.S. (15 How.) 62 (1854);
3. *General Electric Co v Wabash Appliance Corporation* (304 US 364 (1938));
4. *Halliburton Oil Well Cementing Co. v. Walker*, 329 U.S. 1, 12-13 (1946);
5. *Richard A. Williamson v. Citrix Online*, LLC (Fed. Cir. 2015);
6. *Ex parte* Miyazaki, PTAB (2008);
7. Rule 43 (1), Chapter II, Part III, Implementing Regulations to the Convention on the Grant of European Patents, The European Patent Convention;
8. T 0068/85, EPO;
9. F-IV 4.10 Guidelines for Examination, EPO;

process involving an inventive step and capable of industrial application" is wide enough to accommodate functional claiming. The definition only necessitate that an invention should be a new product or a new process involving an inventive step and capable of industrial application. However, Section 10(4)(c) of the Indian Patents Act, 1970 (as amended) which require the claim(s) to define the scope of the invention for which protection is claimed, upon its interpretation may impede claims defined only with functional limitations.[10] The interpretation of Section 10(4)(c) of the Act may be attributed to an Indian patent jurisprudence having tendency to make literal interpretation of claims. This is in contrast with practice of USPTO and EPO which consider structural features recited in the description and place reliance on the ability of a skilled person to infer such structural features. Another, limiting reference comes from the Guidelines for Examination of Patent Applications in the Field of Pharmaceuticals, which consider that functional claiming should be discouraged because such claims lead to confusion regarding the scope of the invention and that in most of the occasions such claims encompass a scope which is inconsistent and much wider to the scope afforded by the descriptions.[11] Owing to specific absence of permissible or qualifying requisites for functional claiming in legal sources, Indian Patent Office (IPO) practice on functional claiming is considerably restrictive than that of the USPTO and the EPO. Claims defined only with functional limitations are often objected by Indian Patent Office for lacking technical features, being unclear and indefinite in their scope. IPO practice related with claim definitiveness require claims to be defined by at least the inventive feature.[12] This may be due to a relatively lower degree of reliance placed on person skilled in the art for the purpose of determining the scope of claims for evaluating definitiveness and enablement requirement as compared to USPTO and the EPO.

Inventions in life science often relate to complex biomolecules, which at times may be difficult to depict by words. This is the reason claims with simple reference to sequence in form of sequence ID is universally accepted. Owing to the complex nature of inventions in life sciences and considering the need to protect the invention with a scope sufficient to cover the trivial structural changes, claims with functional limitations hold specific significance. Functional claims in life sciences, like other claims may, relate to a protein, polypeptide, antibody, or gene. Such functional claims in their extreme form may be considered as 'reach-through' claims, if there exists only a functional relationship among the different biomolecules, but there is no limitation to rescue a person of ordinary skills to derive the entire set of molecules covered by the scope of such claims.[13] Such reach-through claim, like other claims, may be a product claim, a process claim, or a product by process claim. For example, an invention related to identification of peptide, which modulate the activity/function of an important gene/protein, may be drafted as "molecules/agent capable of modulating the activity/function of particular gene/protein" or as "molecules/agent capable of identifying particular gene/protein". Such claims would literally cover all molecules that modulate the activity of the gene/protein as identified in said invention and if no structural limitation is considered for construing the scope of claim, it would also cover future molecules that would perform the same function, or that are possible in theory. The same approach may be translated to process claims, wherein process elements are not defined by their structure but are defined by its function i.e., ability to modulate the expression of a protein or gene. A claim related with production of important biomolecule may be drafted as reach-through claim with a language "A cell culture capable of producing biomolecule with amino acid sequence 1". In such claim if there happens to be no limitations (process or product) related with cell culture, the claim encompasses production of biomolecule with amino acid sequence 1 using any cell culture. There is still another type of functional claims, which are not absolutely 'reach-through' claims but are considered as 'quasi reach-through', as these claims seek to protect molecules, which are not defined by structure but are comparatively confined to be derived using a particular protein or gene.[14] A claim to a mono-clonal antibody against particular protein without structurally defining the antibody, a probe against nucleic acid or amino acid sequence, a cDNA sequence of a gene are examples of quasi reach-through claiming, since such antibodies, probes and cDNA sequences can be reasonably presumed to have been obtained in routine manner by using well-known techniques.

The device of functional claim allows a patent drafter to cover a potentially broad class of structures with a single claim limitation. For example, a claim with broad or generic structural and functional limitation "A peptide capable of treating a cancer", the generic structural limitation construed along with function limitation "capable of treating a cancer" would cover a diverse range of peptides that may interact with diverse target for treating a cancer. Considering that such claim also has additional limitation defining the target of such peptide, such claim on its face would even cover peptide that may not yet have been invented but could interact with said target for treating cancer. Nevertheless, said claim, along with additional limitation defining the target of such peptide, is likely to be considered as 'quasi reach-through' claims, depending upon simplification of techniques involved therein to reach the possible products.

Owing to importance of such claims in life science and the existing vacuum in Indian legal texts to steer functional claiming, Indian Patent office may resort to guiding jurisprudence of US and EP and come up with guidelines to consider functional claiming in a right perspective. Meanwhile, inventions proposed to be protected in India must avoid claims defined only by functional limitations, and must at least define structural feature responsible for ingenuity of subject invention in the claims itself. In other words, the claim language by itself should be sufficient to convey a person of ordinary skill in the art about the structural limitations or process steps encompassed by said claim. The invention must be drafted with sufficient number of dependent claims reciting structural features leading to functional limitation, for the fallback position. This would eventually help in addressing the issues related with the clarity and indefiniteness of the scope of claims during prosecution in general and in particular during invalidation/ infringement proceedings, as the Indian courts have preference to infer the scope of claims by considering the limitation recited in the claims. The description should include sufficient examples to cover range of structural limitations that can perform the claimed functional limitation.

> **"Structural components may be compound, active, biomolecule, nucleic acid, polypeptide, protein, cell lines."**

> **"All of which either fail to recognize functional claiming or provide leeway."**

[10] Section 2(1)(j); Section 10(4)(c) Indian Patents Act;

[11] Paragraph 11.13, page 40, Guidelines for Examination of Patent Applications in the Field of Pharmaceuticals (2014);

[12] Paragraph 05.03.17 k), page 44, Manual of Patent Office Practice and Procedure, Version 3.0 (2019);

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