

ROLE OF AI IN HEALTHCARE AND ITS LICENSING FRAMEWORK IN INDIA

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Abstract

Artificial Intelligence (AI) is a fast and ever-growing field and innovators along with their AI algorithms never fail to astonish the world with their novel inventions. AI has emerged to be a transformative force in the field of healthcare and medicine by way of revolutionary diagnostics, drug discovery, treatment, remote monitoring as well as customized healthcare. AI in healthcare is not a nascent concept and has been in existence since the 1960s. Its evolution over the years has helped AI develop from being a recommendatory tool to a surgery-assisting robot. AI-driven innovations hold the potential to accelerate medical advancements, and pharmaceutical companies around the world have recognized the same. Therefore, AI healthcare applications and devices are being patented to have a monopoly over such applications and devices in their respective technology and area. Further, licensing of such patents can yield economic returns to the inventors as well as investors. This paper explores the key applications of AI in the healthcare sector, particularly in India, and the patent portfolio of a few of the top healthcare companies and their licensing aspects. It further delves into the intricate relationship between AI licensing and software and technology licensing within the Indian Patents Law regime. This will be established through an empirical study of three healthcare companies and their contractual arrangements, dealing with AI components and technologies.

Keywords: Artificial Intelligence, healthcare, licensing, patents.

INTRODUCTION

The involvement of advanced technologies and their contributions to the various sectors of the industry is unmissable. One of the most notable features of such technological advancement is Artificial Intelligence (AI). In recent years, the involvement of AI has been prevalent in the entertainment and communication industries and similarly, AI-assisted technologies have been instrumental in obtaining inventions which are eligible to be protected under the patent laws.

The pharmaceutical sector has witnessed the same convergence and it has given rise to Healthcare Technology or Health-tech Industry or the concept of Digital Health worldwide.

Pharmaceutical companies are very keen on investing in the research and development of this facet as innovation in this sector would bring about a change in human intervention, i.e., a shift towards a more machine-centric arrangement. Unlike the traditional research system carried out by human researchers- pre-clinical and clinical research, utilisation of AI would reduce the time taken to reach the result of the research and would facilitate faster discoveries of both healthcare technologies and drugs. Further, involvement of AI is not only limited to the research stage, it is also capable of providing personalised drugs and treatments to patients. All of this is possible because of the deep supervised machine learning feature of AI, i.e., it can learn automatically, based on the program codes, and even improve itself from experiences. It includes accessing huge amounts of data, depending on which, the intricate algorithms would continuously improve and develop upon.

Currently, patent rights are not granted to an AI as an inventor and the Indian Patents Act, 1970, does not allow for patenting of a software or computer program *per se*¹ unless it is attached to hardware and both are integral components of such invention. Several papers have addressed the issues related to ‘inventorship’ and ‘ownership’ of AI inventions under different patent law regimes. However, the current legislation is not competent to accommodate AI as an inventor because the law only recognises “human inventors”.² Thus, it has been recommended, almost unanimously, that the laws need to adapt to the changing times and make room for AI generated inventions.

Nonetheless, this situation has not discouraged the pharmaceutical companies in India, from implementing AI in healthcare technologies and devices. Indian companies are constantly utilising AI algorithms in their healthcare devices and subsequently getting the system and methods patented as the Patent laws do not allow for patenting of algorithms. Thereafter, in order to commercialise and work the patents in India, companies are generally resorting to licensing mechanisms and arrangements with individuals or third parties, e.g., hospitals, clinics etc. In order to facilitate such arrangements, licensing agreements are required between parties where rights and obligations of both parties are mentioned explicitly. The article thus analyses the role of AI in the healthcare sector along with the patent profiles of three such healthcare companies in India. Thereafter, it discusses the untrodden area of AI licensing arrangements along with the case study of three healthcare companies to understand the common practice of such companies in India.

¹ Section 3(k), The Patents Act, 1970, No. 39, Acts of Parliament, 1970 (India).

² *Stephen L Thaler v. Comptroller General of Patents, Design and Trade Mark*, [2020] EWHC 2412 (Pat).

AI and Its Role in Healthcare

“Artificial Intelligence is a science and a set of computational technologies that are inspired by—but typically operate quite differently from—the ways people use their nervous systems and bodies to sense, learn, reason, and take action. While the rate of progress in AI has been patchy and unpredictable, there have been significant advances since the field’s inception sixty years ago.”³ It was in 1950 that the Deputy Director of the Computing Machine Laboratory, University of Manchester, Alan Turing suggested “the Turing test for identifying a machine to be ‘intelligent’, i.e., in case a human interlocutor is unable to differentiate a machine from another human while being in conversation, the machine is said to have ‘thinking’ abilities.”⁴ However, it was only in 1956 that a Professor at a Dartmouth Conference coined the term ‘artificial intelligence’. He was none other than Professor John McCarthy, also known as the Father of AI and since then it has been founded as an academic discipline.⁵ AI does not have a single universally agreed upon definition and this has acted as a driving force for the field to bloom at such an ‘ever-accelerating pace’.

The field of AI has happened to have seen the most rapid transformations in the field of digital innovations and “after the revolution brought about by steam, electricity and electronics and computers, AI has become an integral part of the Fourth Industrial Revolution”.⁶ So much so, AI systems are viewed primarily as “learning systems; that is, machines that can become better at a task typically performed by humans with limited or no human intervention.”⁷

As mentioned before, there has been a well-defined convergence of AI and Healthcare in the recent past. Thus, it can be expected that the implementation of AI based technology will eventually improve the lives of patients and doctors and hospitals will be able to facilitate better and more affordable healthcare facilities for patients in a time-efficient manner.

The involvement of AI in assisting the healthcare sector, including doctors, in forming better and clearer clinical decisions has been very distinct. It is fair to say that “the increasing

³ Peter Stone et al., *Artificial Intelligence and Life in 2030: One Hundred Year Study on Artificial Intelligence: Report of the 2015-2016 Study Panel*, STANFORD UNIVERSITY, 2016, (Aug. 24, 2023, 11:00 AM) <http://ai100.stanford.edu/2016-report>

⁴ A. M. Turing, I.—*Computing Machinery And Intelligence*, MIND, Volume LIX, Issue 236, October 1950, Pages 433–460, (Aug. 24, 2023, 11:10 AM), <https://doi.org/10.1093/mind/LIX.236.433>.

⁵ WIPO, *Technology Trends 2019: Artificial Intelligence*, (Aug. 24, 2023, 11:15 AM), https://www.wipo.int/edocs/pubdocs/en/wipo_pub_1055.pdf.

⁶ Klaus Schwab, *The Fourth Industrial Revolution*, WORLD ECONOMIC FORUM, 2016, (Aug. 24, 2023, 11:20 AM), <https://www.weforum.org/agenda/2016/01/the-fourth-industrial-revolution-what-it-means-and-how-to-respond/>.

⁷ WIPO, *supra* note 5, at 19.

availability of healthcare data and rapid development of big data analytic methods has made possible the recent successful applications of AI in healthcare. Guided by relevant clinical questions, powerful AI techniques can unlock clinically relevant information hidden in the massive amount of data, which in turn can assist clinical decision making.”⁸

Further, it is inevitable that in the case of human clinical assessments, there would be minute errors, however, the same can be controlled with the help of an AI algorithm whereby the errors are decreased to a large extent to get near perfect results. AI solutions have proved to be time efficient in the case of clinical trials as well because they reduce the period of trials effectively. Moreover, one of the major advantages in this case is that “an AI system extracts useful information from a large patient population to assist in making real-time inferences for health risk alert and health outcome prediction.”⁹ “After the analysis of the genomic data from different patients, AI helps in listing only those patients whose genetic profile suggests it will help them to undergo testing in the clinical trial.”¹⁰ Through the technologies of machine learning, deep learning algorithms and a variety of neural networks, for instance, artificial or computational neural networks, AI solutions have almost revolutionised the process involved in the discovery of drugs and healthcare devices.

From the initial Turing test to AI assisted technologies, AI has indeed come a long way if we consider its present avatar and it still is making huge progress. AI has been employed by various companies in the pharmaceutical sector, namely, IBM, TwoXAR, Insilico Medicine, Atomwise, Berg, GE, Google etc. to obtain certain desired results with the help of machine learning (ML) and deep learning (DL). A few of the healthcare sectors where the role of AI has been most prominent have been discussed below:

1. Discovery and Development of Drugs

The application of AI technology was considered to be unusual in the field of medicine as it was a well-established field already. In 1984, Clancey and Shortliffe provided that “Medical artificial intelligence are primarily concerned with the construction of AI programs that perform diagnosis and make therapy recommendations and unlike medical applications based

⁸ Jiang F, Jiang Y, Zhi H, et al. *Artificial intelligence in healthcare: past, present and future*, STROKE AND VASCULAR NEUROLOGY, 2017 Jun 21;2(4):230-243, (Aug. 25, 2023, 11:25 AM), doi:10.1136/svn-2017-000101.

⁹ Daniel B. Neill, *Using artificial intelligence to improve hospital Inpatient care*, IEEE COMPUTER SOCIETY, 2013, (Aug. 25, 2023, 11:25 AM), <http://www.cs.cmu.edu/~neill/papers/ieee-is2013.pdf>.

¹⁰ VS Nayak et al. *Artificial Intelligence in clinical research*, 3(4), INTERNATIONAL JOURNAL OF CLINICAL TRIALS, 187-193, (2016), eISSN 2349-3259, (Aug. 25, 2023, 11:30 AM), <http://dx.doi.org/10.18203/2349-3259.ijct20163955>.

on other programming methods, such as purely statistical and probabilistic methods, medical AI programs are based on symbolic models of disease entities and their relationship to patient factors and clinical manifestations.”¹¹

It was as early as the 1960s when AI was first introduced in the field of medicine. Expert systems, for instance, the MYCIN (developed by Stanford University), INTERNIST (developed by University of Pittsburgh), CASNET (by Rutgers Research Resource), amongst others, correspond to the growth of AI systems in the medical field. AI had begun as a ‘if/ then rules’ series but it has advanced by leaps and bounds over the years, so much so that currently it includes several complex algorithms which can effectuate in a manner that is similar to that of the human brain. AI has several divisions- ML, DL, and computer vision- which are akin to specialties in medicine. ML is used to identify patterns to analyse a particular situation so that the machine can then ‘learn’ from the same and apply that information to similar future scenarios. This prediction tool can be applied vigorously to clinical decision-making to customise patient care instead of following a static algorithm. “ML has advanced into what is now commonly known as DL, which is composed of algorithms to create an artificial neural network (ANN) that can then learn and make decisions on its own, similar to the human brain and computer vision is a process by which a computer gains information and understanding from a series of images or videos.”¹²

As AI in clinical trials reduces the period of the trial, one of the major benefits of its application is that it consequently minimises the time it takes for a drug to be developed and thereby get approved. It thus makes the drug available in the global market in less time, resultantly, ensuring early access. This further leads to cutting down on cost, thereby, reducing the cost of the medication to provide an affordable treatment facility. For example, novel cancer drug targets can be identified and verified by researchers by using longitudinal EMR (Electronic Medical Records) and other 'omic' data.

Thus, it can be seen that the efficiency of AI in medicine has gone way beyond mere bioactivity predictions since it effectively provides remedies to any setback in the process of discovery of drugs and their development.

¹¹ Enrico W. Coiera, *Artificial Intelligence in Medicine: The Challenges Ahead*, 3(6) JOURNAL OF THE AMERICAN INFORMATICS ASSOCIATION 363-366 (1996), (Aug. 25, 2023, 11:35 AM), <https://academic.oup.com/jamia/article/3/6/363/823662>.

¹² Vivek Kaul, Sarah Enslin, Seth A. Gross, *History of artificial intelligence in medicine*, 92(4) Gastrointestinal ENDOSCOPY, 807-812 (2020), ISSN 0016-5107, (Aug. 25, 2023, 11:35 AM), <https://doi.org/10.1016/j.gie.2020.06.040>.

2. Diagnostics

AI has made remarkable contributions in the field of diagnostics. So much so, radiology is one such department where AI has succeeded in replacing human judgment in healthcare. In 2015, “Capitol Health Limited, an Australian radiology service company, and Enlitic, a medical start-up, announced their first collaboration on the end-to-end transformation of medical diagnostics using deep learning technologies for radiologists and healthcare providers.”¹³ In 2017, “Stockholm3 test, a blood-based prostate cancer diagnostic test was launched by a team at Karolinska Institutet and it is being clinically practiced in Sweden, Norway, Finland and Denmark.”¹⁴ Further, in January 2020, it was discovered by a team of researchers in Sweden that an AI platform has the capability to diagnose prostate cancer accurately in tissue samples.¹⁵

While such developments are taking place globally, the role of AI in healthcare can be seen to be expanding in India as well. Along with Microsoft and Forus Health, NITI Aayog is working to roll out a technology that would help in the ‘early detection of diabetic retinopathy’ as a pilot project. Forus Health has developed a portable device called ‘3Nethra’ and it can be used to detect eye problems. “Integrating AI capabilities to this device using Microsoft’s retinal imaging APIs enables operators of 3Nethra device to get AI-powered insights even when they are working at eye check-up camps in remote areas with nil or intermittent connectivity to the cloud and the resultant technology solution also solves for quality issues with image capture and systems checks in place to evaluate the usability of the image captured.”¹⁶

Few of the AI systems which have been developed in the recent past in the field of healthcare and medicine¹⁷:-

¹³ Jeremy Howard, *Enlitic and Capitol Health Announce Global Partnership*, (Aug. 25, 2023, 11:40 AM), <https://www.enlitic.com/enlitic-and-capitol-health-announce>.

¹⁴ Nathan Eddy, *AI platform helps diagnose prostate cancer, Lancet report shows*, Healthcare IT News, (Aug. 25, 2023, 11:40 AM), <https://www.healthcareitnews.com/news/ai-platform-helps-diagnose-prostate-cancer-lancet-report-shows>.

¹⁵ Nathan Eddy, *AI platform helps diagnose prostate cancer, Lancet report shows*, HEALTHCARE IT NEWS, (Aug. 25, 2023, 11:40 AM), <https://www.healthcareitnews.com/news/ai-platform-helps-diagnose-prostate-cancer-lancet-report-shows>.

¹⁶ NITI Aayog, *National Strategy for Artificial Intelligence*, June 2018, (Aug. 25, 2023, 11:42 AM) <https://indiaai.gov.in/documents/pdf/NationalStrategy-for-AI-Discussion-Paper.pdf>.

¹⁷ Kavita Sharma and Padmavati Manchikanti, *Regulation of Artificial Intelligence In Drug Discovery and Healthcare*, 39(5) BIOTECHNOLOGY LAW REPORT, 371-380 (Oct. 7, 2020), (Aug. 25, 2023, 11:45 AM) <http://doi.org/10.1089/blr.2020.29183.ks>.

Institution/Company	Name of the AI system and Year of development	Target solution(s)
IBM	IBM Watson (2010)	Data support
Microsoft	Microsoft Azure (2010)	Health cloud platform
Google Brain	TensorFlow (2015)	Open-source software library for data
Siemens	Siemens Healthineers Digital Ecosystem (2017)	Platform for data, applications and services
Infosys	Infosys Nia™ (2017)	AI tool for predictability and solving complex problems
IBM	IBM Genomics (2018)	Precision Medicine
Philips	Intellispace Discovery (2018)	AI platform for radiology

3. Electronic Medical Records (EMR)

ML systems are used to gather, process as well as analyse the healthcare data of patients and healthcare facilities around the world are using the AI algorithm to store such data securely in a centralised storage cloud or system. This is known as the Electronic Medical Records (EMR). Many a times, doctors refer to such records to comprehend the effect of a specific genetic trait or medicine on a patient's health. Since ML technologies are competent to process and analyse large amounts of data, they can generate real-time results for diagnostic purposes and thereby help in providing proper treatment to the patients. One such example is that of Cleveland Clinic, where researchers developed "an artificial neural network that analyses lung cancer patients EMRs and medical scans to determine the most effective radiation dosage for therapy."¹⁸

4. Health Insurance

The application of AI is increasing in the health insurance industry as the insurance sector is facing various challenges including privacy concerns and increases in costs. Thus, AI

¹⁸ Bin Lou, et al., *An image-based deep learning framework for individualising radiotherapy dose: a retrospective analysis of outcome prediction*, THE LANCET DIGITAL HEALTH, (Aug. 25, 2023, 11:47 AM), [https://doi.org/10.1016/S2589-7500\(19\)30058-5](https://doi.org/10.1016/S2589-7500(19)30058-5).

algorithms are being used in determining the risks and premiums, detecting and preventing fraud, accelerating claims, and improving the experience of customers overall. Artivatic.ai is an Indian AI based insurance platform. It provides “next-generation insurance products and solutions to simplify risk assessment, process automation & digital use to enable access to insurance.”¹⁹

5. Remote monitoring

Another breakthrough in the contribution of AI in the healthcare sector is that of remote monitoring and support of patients. Numerous pharmaceutical organizations have effectively developed wearables, such as watches, which the AI algorithms control and these wearables can distantly monitor patients who are suffering from fatal diseases.

For example, Tencent Holdings has teamed up with Medopad to build an AI innovation that can distantly screen patients with Parkinson's sickness and diminish the time taken from thirty minutes to three minutes to perform a ‘motor function assessment’. This particular AI technology, incorporated with cell phone applications, makes it feasible to monitor the ‘opening and closing movements’ of a Parkinson's patient's hands from a distant location. Based on this, the severity of the patient will be determined which in turn will allow the doctors to regulate or revise the dosage of the drugs remotely and in case the condition worsens, an alert will be sent to the doctor for a check-up by the AI technology, thereby saving the problems related to patients travelling for check-ups in emergencies.²⁰

Further, Pfizer, recently, in association with robotics company Catalia Health, has also announced that it will launch a “one-year home robot program that uses voice interactions powered by conversational AI to assess a user’s mood, record data, manage symptoms, and provide helpful information about prescription drugs.”²¹ The pharmaceutical corporation has also collaborated with Sidekick-Health in order to commence a “digital medication management platform” across Europe.²²

¹⁹ Artivatic [AI Insurtech & Healthtech], <https://artivatic.ai/about-us> (last visited Sep. 06, 2023, 11:47 AM).

²⁰ Marcus Lawrence, *Tencent seeks out Britain's Medopad to develop AI-based treatment of Parkinson's disease*, TECHNOLOGY MAGAZINE, (Aug. 25, 2023, 11:47 AM), <https://www.technologymagazine.com/ai/tencent-seeks-out-britains-medopad-develop-ai-based-treatment-parkinsons-disease>.

²¹ Pfizer, *Enhancing Patient Care Through Digital Transformation*, PFIZER 2019 ANNUAL REVIEW (Aug. 25, 2023, 11:47 AM), https://www.pfizer.com/sites/default/files/investors/financial_reports/annual_reports/2019/our-bold-moves/win-the-digital-race-in-pharma/enhancing-patient-care-through-digital-transformation/index.html.

²² Susan Kelly, *Sidekick, Pfizer team on digital therapeutic for chronic disease*, MEDTECHDIVE (Aug. 25, 2023, 11:49 AM), <https://www.medtechdive.com/news/sidekick-pfizer-team-on-digital-therapeutic-for-chronic-disease/580808/>.

Other applications of AI in healthcare include robot-assisted surgery²³, epidemic prediction, identifying candidates for clinical trials, drug dosage and precision, sales and marketing²⁴, administrative assistance amongst many others.

Patents Related to AI in Healthcare

There are a rich number of AI start-ups in healthcare in India which are involved in diagnostics, insurance, screening etc. for various chronic diseases. This study also aims to look at the patent profiles of a few of such healthcare start-up companies which are making a mark in the Indian healthcare sector. Most of the patents are filled through the PCT route and the subject matter of protection of the AI assisted technologies in the healthcare field mostly focuses on the system and method of the invention.

- **Niramai Health Analytix Private Limited**

Geetha Manjunath founded Niramai in 2016 and it has developed to be a novel breast cancer screening solution provider. The solution is a “low cost, accurate, automated, portable, radiation-free, non-touch and non-painful cancer screening tool that can be operated in any clinic.”²⁵ Niramai’s exceptional AI solution is used at various hospitals and clinics, in urban and rural areas, for the diagnosis of cancer, including preventive health checkups. The profiles of a few of the active and pending patents filed by Niramai are as follows:

NIRAMAI HEALTH ANALYTIX PRIVATE LIMITED					
PATENTS					
SL. NO.	PUBLICATION NO.	TITLE OF INVENTION	IPC ORIGINAL	DATE OF GRANT	STATUS
1	20200352452	SYSTEM AND METHOD FOR ADAPTIVE POSITIONING OF A SUBJECT FOR CAPTURING A THERMAL IMAGE	A61B-5/0008	2022-12-27	ACTIVE

²³ Philips, *Philips Azurion System*, (Aug. 25, 2023, 11:49 AM), <https://www.philips.co.in/healthcare/product/HCNV003/azurion-7-c12-azurion-7-f12-image-guided-therapy-system>.

²⁴ PharmEasy, <https://pharmeasy.in/> (last visited Sep. 06, 2023, 11:47 AM).

²⁵ Niramai Health Analytix Private Limited, <https://www.niramai.com/> (last visited Sep. 06, 2023, 11:47 AM).

2	20170245762	PRIVACY BOOTH FOR BREAST CANCER SCREENING	A61B-5/0046	2020-11-10	ACTIVE
3	20160283658	SOFTWARE INTERFACE TOOL FOR BREAST CANCER SCREENING	A61B-5/72	2018-08-21	ACTIVE
4	20220237781	SYSTEM AND METHOD TO GENERATE DISCRETIZED INTERPRETABLE FEATURES IN MACHINE LEARNING MODEL	G06T-7/0012		PENDING
5	20220287570	SYSTEM AND METHOD FOR IDENTIFYING ERRORS IN POSITIONING OF A SUBJECT FOR CAPTURING A THERMAL IMAGE	A61B-5/015		PENDING

- **SigTuple Technologies Private Limited**

SigTuple, founded by Rohit Pandey, Tathagato Dastidar and Apurv Anand in 2015, implements AI and robotics to make smart diagnostic solutions. The AI platform helps in the screening of five tasks: “Analysis of peripheral blood smears; OCT scans and chest X-rays; Semen screening; Urine microscopy; Fundus screening.”²⁶ Around twenty-four patent applications were filed by SigTuple and a few of them have been listed below:

²⁶ SigTuple Technologies Private Limited, https://sigtuple.com/?page_id=2698 (last visited Sep. 06, 2023, 11:47 AM).

SIGTUPLE TECHNOLOGIES PRIVATE LIMITED

SIGTUPLE TECHNOLOGIES PRIVATE LIMITED					
PATENTS					
S. NO.	PUBLICATION NO.	TITLE OF INVENTION	IPC ORIGINAL	DATE OF GRANT	STATUS
1	20210405339	METHOD AND SYSTEM FOR AUTO FOCUSING A MICROSCOPIC IMAGING SYSTEM	G02B-21/244	2022-05-24	ACTIVE
2	20200205790	METHOD AND SYSTEM FOR DETERMINING QUALITY OF SEMEN SAMPLE	A61B-10/0058	2021-01-05	ACTIVE
3	201941044248	A MICROFLUIDIC CARTRIDGE FOR SMEARING BIOLOGICAL FLUID	B01L-003/50	2021-01-01	ACTIVE
4	201941052059	A MECHANISM FOR POSITIONING A SAMPLE SLIDE IN A DIAGNOSTIC DEVICE	A61F-002/966	2020-07-10	ACTIVE
5	201941052059	A MECHANISM FOR POSITIONING A SAMPLE SLIDE IN A DIAGNOSTIC DEVICE	A61F-002/966		PENDING
6	201941011025	METHOD AND SYSTEM FOR AUTO FOCUSING A DIGITAL MICROSCOPE	G02B-021/00	2020-01-03	ACTIVE
7	201841049496	METHOD AND SYSTEM FOR GENERATING A	A61B-003/00		PENDING

		STRUCTURE MAP FOR RETINAL IMAGES			
8	201941044248	A MICROFLUIDIC CARTRIDGE FOR SMEARING BIOLOGICAL FLUID	B01L-003/50		PENDING
9	201841013568	METHOD AND SYSTEM FOR DETERMINING TOTAL COUNT OF RED BLOOD CELLS IN PERIPHERAL BLOOD SMEAR	G01N-001/2813	2019-11-01	ACTIVE
10	201641033732	METHOD AND SYSTEM FOR IMAGE ACQUISITION AND ANALYSIS OF A MULTI-LAYERED SAMPLE	H04L-029/00	2019-09-20	ACTIVE

6.

- **Tricog Health India Private Limited**

Tricog was founded in 2014 by Dr Charit Bhograj, an Interventional Cardiologist. At Tricog, critical cardiovascular problems are detected and healed by AI technology along with human proficiency. Most of the time cardiac issues become life-threatening due to delays in detecting them. With the help of AI, the medical team at Tricog can identify such issues well within time. Currently, the groundbreaking AI has a data store that provides more than two hundred cardiac conditions, which radically improves the detection mechanism of rare cardiac issues.²⁷ The patent profile of the company has been provided as under:

²⁷ Tricog Health India Private Limited, <https://www.tricog.com/about-us/> (last visited Sep. 06, 2023, 11:50 AM).

TRICOG HEALTH INDIA PRIVATE LIMITED					
PATENTS					
S. NO.	PUBLICATION NO.	TITLE OF INVENTION	IPC ORIGINAL	DATE OF GRANT	STATUS
1	20220202341	A SYSTEM AND METHOD FOR DETECTING PACER SPIKES TO DETERMINE A PACED RHYTHM IN ECGS	A61B-5/7203		PENDING
2	20220175322	SYSTEM AND METHOD FOR ADAPTIVE INTERFERENCE SUPPRESSION	A61B-5/318		PENDING

- **Qure.ai Technologies Private Limited**

Founded by Prashant Warier in 2016, Qure.ai is one of the leading AI based healthcare companies in India. It aims at making healthcare accessible and affordable with the application of its breakthrough AI solution. It develops “deep learning algorithms that interpret radiology images” and the products help “identify and localize abnormalities on X-rays, MRI and CT scan”.²⁸ It has made significant progress in the field of radiology and has been able to provide a faster diagnosis in order to facilitate speedy treatment. It has filed a number of patent applications and many of them have already been granted. A few of them have been provided hereunder:

²⁸ Qure.ai, <https://qure.ai/> (last visited Sep. 06, 2023, 11:50 AM).

QURE.AI TECHNOLOGIES PRIVATE LIMITED					
PATENTS					
S. NO.	PUBLICATION NO./ PATENT NO.	TITLE OF INVENTION	IPC ORIGINAL	DATE OF GRANT	STATUS
1	11636596 (PATENT NO.)	MONITORING BRAIN CT SCAN IMAGE	G06T-7/11	2023-04-25	ACTIVE
2	20210327055	SYSTEMS AND METHODS FOR DETECTION OF INFECTIOUS RESPIRATORY DISEASES	G06F-40/30	2022-04-19	ACTIVE
3	20200151871	APPLICATION OF DEEP LEARNING FOR MEDICAL IMAGING EVALUATION	G16H-30/40	2020-08-04	ACTIVE
4	10755413 (PATENT NO.)	METHOD AND SYSTEM FOR MEDICAL IMAGING EVALUATION	G06N-3/08	2020-08-25	ACTIVE
5	20230177687	AUTOMATICALLY DETERMINING A BROCK SCORE	G06T-7/0012		PENDING

Thus, it can be observed that the healthcare companies have a rich patent profile and the patents give rise to the possibilities of sharing the technology to make the products available in the market. Further, for better research and development, there arises the requirement of licensing or collaborating with other organisations, such as hospitals, clinics etc., and it is a known fact that AI thrives on data. Thus, for healthcare companies to develop an AI solution and make it functional, it is important to have some kind of arrangement with hospitals or laboratories in order to collect the required data and carry out pilot trials. Further, to make such technologies or devices work in the country, the said companies need to enter into certain arrangements. The most preferred method for sharing such patented works is licensing, whereby, the licensee will be able to use the technology while the licensor retains his ownership rights and earns royalty.

Thus, it becomes important to understand the framework of AI licensing.

AI Licensing Framework

The WIPO Conversation on IP and AI, 2019, aims to provide a policy dialogue on AI's impact on IP rights.²⁹ It highlights the significance of data for AI and the Member countries have raised concerns about data access and sharing. They have suggested that WIPO provides certain licensing guidelines. The report highlights AI's pivotal role in digital innovation and the rise of AI-related patents. It also advocates for public-private partnerships, and open sharing of AI resources, to promote better AI understanding. However, the report does not discuss any contractual or licensing framework for sharing AI technology and thus one needs to rely upon software and technology licensing to make AI licensing arrangements.

In the case of software and technology licensing, there are certain things which need to be considered if compared with other contracts.³⁰ Unlike in the case of other contractual arrangements, technology licensing only occurs “when one of the parties owns some valuable intangible IP.”³¹ Such licenses may only be for “certain IP rights (license to practice an identified patent)” or for “all IP rights which are required to make, use, reproduce or sell products based on a type of technology (license to develop a new software protected by patent)” or “all IP rights which are essential to develop and sell a product that complies with a technical standard or specification on FRAND terms”.³² Such licenses, unlike other contracts, involve more than the straightforward question of ‘how much?’ The aim here is to strike a fine balance of value so that the license is a ‘win-win’ transaction. In order to acquire the technology rights, the licensee too has to offer something of equal value to the licensor and there is an exchange of different elements, namely, “skilled workers, a commercially viable market, research facilities or some other form of IP”.³³

Further, along with defining the objective of the license, clauses in software and technology licenses include a “description about the technology, its usage, rights related to any pre-existing and newly created IP during the license period, and also over any product obtained using the technology, so on and so forth.”³⁴ These agreements are not only for the material transfer of

²⁹ WIPO, *WIPO Conversation on Intellectual Property (IP) and Artificial Intelligence (AI)*, 2019, (Aug. 27, 2023, 11:30 AM), https://www.wipo.int/edocs/mdocs/mdocs/en/wipo_ip_ai_ge_19/wipo_ip_ai_ge_19_inf_4.pdf.

³⁰ WIPO, *Successful Technology Licensing*, IP ASSETS MANAGEMENT SERIES (Aug. 27, 2023, 11:30 AM), https://www.wipo.int/edocs/pubdocs/en/licensing/903/wipo_pub_903.pdf.

³¹ *Id.* at 5.

³² WIPO, *supra* note 30, at 6.

³³ WIPO, *supra* note 30, at 6.

³⁴ WIPO, *supra* note 30, at 6.

the technology but also includes practical know-how, such as, the licensee being provided with training as to how to utilize the technology in an effective manner.

In relation to AI software, the chief intention behind the licensing arrangement is to ‘protect the interest’ of the owner of the software (IP) while granting certain rights to the user. The major concern in relation to AI is the data and the concerns related to ownership and protection of such data. Thus, special attention is paid while drafting and entering into AI licensing agreements by licensors.

The licensing agreement includes clauses related to the usage and restrictions related to the software, the licensee or the user's rights in relation to modifying or redistributing it, conditions of breaches, indemnity clauses and jurisdictional aspects in case a dispute arises in the future. By and large, licensing can be of two types, namely:

- i. **Exclusive Licensing** – Here, the ownership is transferred by the patent owner who simply retains the title and nothing else. However, the license is exclusive to the licensee and thus cannot be licensed out further by the licensee. Similarly, the licensor also faces a disadvantage as the licensee would exert all IP rights to the exclusion of all, even the licensor. Even though the royalty paid to the licensor is a lot higher in this kind of arrangement, it is not a popular practice amongst healthcare companies.
- ii. **Non-exclusive Licensing** – This type of licensing allows the licensor to grant the license to more than one licensee. While one licensee may exploit the rights granted to him, he cannot exclude others under this arrangement because the license has not been granted to him exclusively. It allows all the licensees to exploit the patented invention equally, against a certain amount of royalty or license fee. Non-exclusive licensing is the most preferred way of licensing which is practiced by the owners and is most relevant in the case of patent licensing of AI in healthcare.

Case Study of AI Based Healthcare Company

If one looks at the development of industry in this area, there is no one category of company type. Several start-ups and small firms with unique AI technologies have been bought over by several Indian entrepreneurs. Therefore, in order to understand the general practice amongst the healthcare companies, case studies of three companies have been conducted based on their AI technology-sharing agreements. Companies A, B and C deal with smart screening solution; underwriting, insurance and health assessment; and breast cancer diagnosis, respectively.

1) Company A:

The said company implements AI, robotics and data science to develop ‘smart screening solutions’ in order to provide accurate, accessible and affordable healthcare devices. Their business structure is based on selling these devices to hospitals or institutions whereby there is a cost for the hardware and also for the continued usage of AI. Company A provides cloud service to the hospital, data management, and also provides updates on the AI solution. Therefore, the licensing includes Software as a service (SaaS). Further, Company A collaborates with reputed hospitals to validate and improve the consistency of the technology; consult with medical practitioners to analyse the data and carry on clinical evaluation of the diagnostic products. These collaborative projects are done in an efficient and time-bound manner. A few of the peculiarities that are involved in relation to AI licensing agreement in this case have been discussed hereunder:

- i. **Ownership and use of the AI solution:** Company A is the owner of the IP, including the AI solution used in the AI devices, which had been developed before the arrangement and similarly, any IP owned by the hospitals would be the property of the hospital itself. The hospitals would only have the usage rights, strictly on a non-exclusive basis, in relation to the AI devices and solutions and not ownership rights. However, any kind of publication that is related to the arrangement shall be jointly authored and owned, providing due credit for their contribution and expertise.
- ii. **Ownership, usage of training and production data:** In the interview as well as in the agreement shared, it was mentioned that Company A uses the patient data owned by the hospitals after complying with the applicable data protection and privacy laws of the country. However, in relation to the production data, i.e., the data and images generated from using their devices, it is typically retained by Company A for the purpose of R&D and improving the solution.
- iii. **Ownership and use of AI output and evolutions:** It is one of the most important aspects of AI licensing arrangements. It has been explicitly laid down in the agreement that the hospitals are allowed to use the IP (any output or improved solution) for their internal business purposes but it shall be on a ‘non-sublicensable, non-payable, non-transferable, nonexclusive, non-perpetual and revocable’ basis. On the other hand, any forward IP, including any solutions or derivatives (tangible or intangible), developed during the arrangement period, would completely vest upon Company A ‘perpetually, irrevocably and royalty-free’.

7.

2) **Company B:**

8. The said company's expertise in providing software and product solutions using AI, ML or data science, namely, but not limited to, 'distribution, underwriting, claims, document processing, intelligence, risk & fraud, sales & marketing, health assessment etc. for insurance, healthcare & financial services' by way of cloud services (SaaS). Company B is generally engaged by customers (insurance companies) to provide smart underwriting & decision-making with alternative data from time to time in pursuance of a service agreement. Thus, on perusal of Company B's agreement with the customer, the following particulars have been identified:

- iv. Ownership and use of the AI solution: During the interview as well as in the agreement, it has been enunciated that Company B has ownership of any pre-existing software or IP, including the AI solution which is incorporated in the output obtained (work product). After complying with any legal requirement, the customer is granted the rights to use such IP on a royalty basis, non-exclusive, time-bound manner and also a sub-licensable license. It was further provided that materials containing any proprietary information are to remain the sole and exclusive property of the party disclosing the same without granting the other party any licence or ownership of any type over such materials.
- v. Ownership, usage of training and production data: The agreement provided that during the service period, the confidential data used by Company B to provide services would be purged on a regular basis. On expiration/termination of the service period, Company B has to delete all such data from its system. Unlike the previous case, here the customer owns the data and Company B is bound to return and permanently delete any such data, including electronic data, which cannot be recovered using forensic or any other method. In case the data cannot be returned, a data destruction certificate has to be provided by Company B.
- vi. Ownership and use of AI output and evolutions: In this case, as per the agreement, the work outputs are deemed to be works for hire. Therefore, the customer has exclusive ownership over all rights, titles and interests in all the outputs and IP, including all 'web assets, software, designs, systems or concepts' which are developed by Company B, solely or jointly with the customer. However, the customer does not have the right to

share or grant its affiliates, holding company or companies and their respective subsidiaries and branches any of the work output obtained as a result of Company B's services.

9.

3) **Company C:**

The Company's core solution is an AI-powered computer-aided diagnostic engine. It uses a 'high-resolution thermal sensing device and a cloud hosted analytics solution' for the purpose of analysing the thermal images. The company has developed a SaaS solution for early and accurate breast cancer screening. This has led to the grant of multiple US patents and till now the company has successfully screened more than 35,000 women for breast cancer in various hospitals/diagnostic centres and screening camps. Clinical trials have been conducted and the results indicate that the AI solution has a very high accuracy in analysing breast health conditions and at times it has performed better than mammography as well.

Further, the company has a web interface for the company's certified technicians so that they can upload the demography information as well as the thermal images of the patients. The said information is then processed by the patented technology and the solution then a report is generated automatically which would list definite unique parameters and also recommend a 'breast health score' based on the thermal images. The customers have the option to avail the company's expert opinion, at additional expenditures or are free to employ their expert Radiologist for the certification of the reports.

During the interview, it was mentioned that the company entered into MOUs- Clinical Trial Agreements- with hospitals to collect the data and conduct research studies for the AI solution. The terms and conditions related to all the components are laid down in the MOU, including declarations to abide by the privacy concerns of the data and protect the interest of the patients.

- i. **Ownership and use of the AI solution:** As per the terms of the MOU, it has been laid down that any background IP present at the time of entering into the agreement would be owned by the respective parties. Therefore, Company C has sole ownership over the AI solution and hospitals or clinics are only given the usage rights. In the case of any foreground IP, i.e., 'project IP', it depends upon the arrangement between the parties and it was mentioned that ideally, the Company avoids the development of any patents in clinical trials, to avoid any loss of IP. Any IP (copyright) arising from any publication is jointly authored and co-owned by the parties. However, if the MOU is associated with

financial transactions, i.e., the study is being sponsored by the Company then typically it would be the Company having the ownership right as the company is paying for the study. Further, in case the hospitals are employing their own radiologists, training is given to the concerned person but only the usage of the technology is revealed and nothing more, in order to protect the Company's patented technology.

10. Here, it is necessary to mention that the MOU does not contain any clauses on exclusivity and it only lays down the purpose of the collection of the data and the purpose of the study.

- ii. Ownership, usage of training and production data: One has to rely upon the terms of the MOU to answer 'Who owns the data?' In this case, the Company has to first describe and place a proposal before the Ethics Committee of the hospital and declare why the data is being sought and who shall collect the same; what kinds of tests are to be done based upon the data without causing any harm to the patient. Once the proposal is approved, data is collected by the company for the study. Now, in case it is a research collaboration to train a model or test a model, the training data is owned by the hospital and the Company only has the right to use both the training and production data for research purposes. If any of the production data is to be used for commercial purposes, the hospitals need to agree to the same and the terms of the MOU should also mention the same. However, many a times the data is commercially provided in a corporate camp or clinical camp and the Company employs its AI solution as a service to the entity. In this case, a consent form is required from the end users whereby it will be explained why the images are being taken and whether the patient is in good health or otherwise.

11. However, again, if the study is being sponsored by the Company, then it may seek ownership over the production data as there are monetary considerations attached to the data collection and study.

- iii. Ownership and use of AI output and evolutions: As the ownership of the AI technology remains with the Company throughout, and as already seen the purpose of the study is to either train or test a model, the output and evolutions are also owned by the Company. However, in case of any commercial engagement, the right to the cancer screening product with AI technology is granted by way of the sale of the product.

Therefore, it can be observed from the above analysis that different companies have different sets of arrangements with their respective customers in relation to the ownership, usage of training and production data and also the AI output and evolutions. There is no straight-jacket

formula or any legislative framework that can be applied by the companies. This gives rise to a tricky situation for the companies to operate and share their AI assisted healthcare technologies in India. Along with such legislative challenges, the AI healthcare industry in India faces several other challenges, namely, regulatory requirements, ethical concerns, funding, infrastructure and cyber security concerns amongst others.

Conclusion

The era of digitisation has helped expand the role of AI solutions and it has surely become a tool of assistance in healthcare, especially in the case of AI assisted diagnostics. Healthcare companies, around the globe, are developing novel inventions relating to drugs and devices in the healthcare sector. India has several disruptive start-ups which are engaged in AI based diagnostics which provide solutions to detect breast cancer, a platform for radiologists to visualize and quantify medical images to diagnose diseases, monitor and manage healthcare data, fitness and nutrition apps and even personalised plans to help identify and deal with mental health issues. As a result, there is an increase in the growth of patenting of methods and systems of such AI solutions in the healthcare sector.

It has been observed that AI based healthcare companies are rich in patent profile and companies regularly upgrade their AI solutions to achieve specific and better results. However, since the Patents Act, 1970 does not allow for patenting of the AI algorithms, it at times poses difficulty which the companies have been trying to overcome. In order to align with the existing legislation, the companies develop the AI technologies along with the devices and the same is patent protected. Thereafter, the AI based healthcare device is shared with third parties.

It has been further observed that non-exclusive licensing is the most favourable mode of licensing as practiced in the healthcare sector. However, AI licensing has certain peculiarities which are different from software and technology licensing. AI licensing is much more complex and specialised. It is completely dependent upon data, unlike software and technology licensing and the discussion on data itself requires a detailed separate study. Since a lot of data-based applications are part of AI solutions, a lot of customisation is done to the original application. Subsequently, such evolution of the AI solution gives rise to the development of project IPs or foreground IPs. Thus, in the case of AI licensing, along with the standard clauses, companies need to be very specific about the ownership rights over various components of AI- AI solution, training and production data, AI output and evolutions. The effectiveness of the licensing agreements in terms of 'assigning back' or 'licensing back' depends on the extent of

collaboration or joint development arrangements between the parties.

The case studies have been instrumental in understanding the practical aspect of sharing such AI based healthcare technologies in India and it can be reiterated that there is no particular set of rules or regulations which govern AI licensing arrangements. It currently depends on the nature of the AI solution and also on the company and its customers. However, it is desirable to have a framework for the licensing of AI solutions in India, because, without a framework, the risks of losing out on forward IP are huge. This may be achieved with the help of explicit guidelines and a dedicated regulatory authority which would be responsible for setting the standards, issuing of licences and ensuring overall compliance.