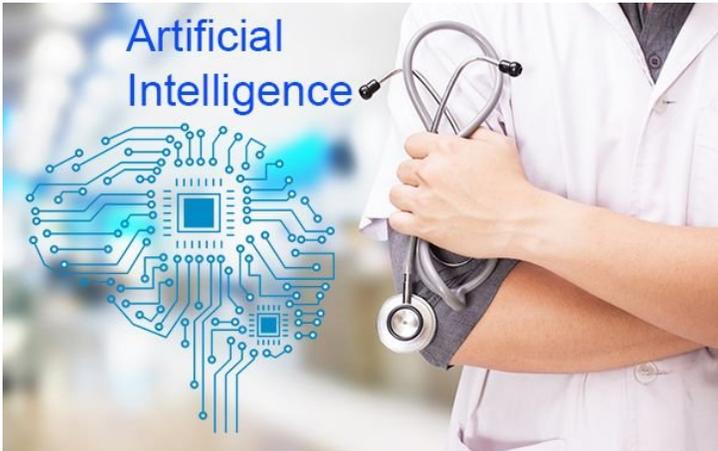# AI based health innovation in India - a legal perspective

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Indian health care industry is an early adopter of AI technology

Artificial intelligence (AI) involves the simulation of intelligent human behavior in computers. AI, once a mere posterchild of sci-fi novels has now arrived with aplomb and is all set as a technology platform that drives innovation across board. Not only is it making headlines in the IT and computer science industry, it is also revolutionizing the way innovation is driven in the ever-complex biotechnology and health care sector. AI is significantly impacting innovation in the area of personalized genomic medicine, drug discovery, drug target identification and validation, biomedical, clinical and patient data management, drug repurposing programs and biomarkers development.

Adoption of AI based technology by Indian healthcare system

While certain industries are still trying to explore what AI can do for them, interestingly, the Indian health care industry is an early adopter of AI technology. A visible shift towards AI- based healthcare management can be seen in some of the key health care institutions. One prominent indicator of this is some of these institutions partnering with AI-focused start-ups. AI-based software platforms are increasingly being used by hospital networks for patient data analysis and diagnosis. Manipal hospitals, is using IBM's 'Watson for oncology' for personalized cancer therapy. Cardiotrack, an AI-based start-up has collaborated with Paras Hospital in Delhi ncr, Star hospital in Ahmedabad and Columbia Asia in Bengaluru. They have developed hand-held devices that analyze patient ecg data to prognose cardiac disorders using AI-based algorithms and a medically curated database of 500,000 ecg scans. On the other hand, companies like Microsoft India have forayed into healthcare with initiatives such as the "healthcare next" and "Microsoft intelligent network for eyecare (mine)" and is collaborating with the government of Telangana for visual impairment screening. Start-ups such as Healthi and Inito are employing predictive analytics, personalization algorithms and machine learning to deliver personalized health solutions.

India's recognition as global leader in AI based innovation

A latest report by World Intellectual Property Organization (WIPO) - technology trends 2019 has reported a massive rise in AI-based inventions with China and the U.S. leading research in the field of AI. It notes that the patent office's receiving highest number of patent filings in the AI field are France, Germany, the Republic of Korea and the U.K. India is emerging as a key

player occupying the 10th position worldwide for the number of AI-based patent applications and 4th for publications respectively. The report observes that "while it does not appear among the top offices for patent filing, India ranks third in fuzzy logic and fourth in machine learning scientific publications." Thus, in contrast to China and US, a gap between research publications and patent filings exists in India that needs to be addressed. Further, healthcare was recognized as a key sector in the report where AI can bring positive transformation.

Government initiatives to boost innovation in AI

Special efforts are being undertaken by the Indian government to cement India's firm presence as an innovator in AI technology. In the 2019 budget speech earlier this month, the finance minister announced the establishment of the national center on Artificial Intelligence as a hub along with centers of excellence and development of a national Artificial Intelligence portal. The Ministry of Commerce and Industry has also established an Artificial Intelligence task force to create policy and legal framework to accelerate deployment of AI technologies. Economic planning think-tank: NITI Aayog has already been mandated to establish a national program on Artificial Intelligence and healthcare and agriculture have been identified as areas of special interest for increased access and affordability of quality healthcare and enhanced farmers' income, increased farm productivity and reduction of wastage respectively. Government has further proposed establishment of IPR facilitation centers to help bridge the gap between practitioners and AI developers, and adequate training of IP granting authorities, judiciary and tribunals. Further, the definition of start-ups has been amended as per the patent rules to allow a biotechnology-based start-up to avail an extended 10 years of start-up status including foreign entities. Start-ups are further given special incentives at the Indian patent office such as lower cost of patent filing and expedited examination.

Challenges in protecting AI inventions in India

At the societal level, AI driven technology is developing fast and is interpolating in an ever-pervasive way into not only commercial and industrial processes but also the personal lives. This has posed several unique ethical and legal issues including those concerning the patent law.

Who is the inventor

With the advent of sophisticated AI-based algorithms, the threshold of inventiveness as per the law can now be easily passed by the algorithm itself. This poses an interesting legal conundrum as to who is the inventor and owner of the invention. By law, algorithms do not have legal personhood ascribed to them. Therefore, the question arises whether the person who created the AI algorithm or the entity that is employing the AI to solve a given problem deemed to be the owner or for the lack of a legal inventor, the invention passes into public domain?

Whether AI can be patented?

Further, under section 3 of the Indian Patents Act, algorithms can only be patented when utilized in tandem with a hardware component to create a practical technical effect. Thus, the patenting of the algorithm per se is not allowed. Further challenges arise when the AI technology finds application in biotech/life science industry. The prevailing patent practice tends to reject diagnostic or prognostic technologies by viewing them as methods to treat diseases that are barred in India. Thus, the patentability of AI based applications covering a method of analysis of patient data and arriving at personalized disease treatment poses a challenge at present. Further, clarity is required from the adjudicating authorities to distinguish an application that prognoses diseases based on AI by utilizing medical databases from direct treatment methods.

AI and drug discovery/ biotech: the higher patentability threshold

Although AI based innovation can arrive at potential inventions, the invention has to be practically authenticated with working examples to be deemed patentable. In the field of biotechnology, a derivative product or a process also needs to experimentally demonstrate unexpected effects or higher efficacy threshold. The law further requires that the description of an invention be unambiguous and detailed, describing the best method of performing it. Thus, AI based drug discovery would always require further lab testing and experimental data to cross the patentability threshold in India.

The European patent office has recently issued specific guidelines for the examination of Artificial Intelligence and machine learning based invention. A similar initiative in India would further boost patenting and fill the already discussed lacuna between publications and patent applications in India.

Alternative forms of IP protection for AI related inventions

Other legal considerations

Industry has traditionally relied on patents as the strongest IP right to protect innovation and secure commercials. However, as explained above, Indian patent law has inherent statutory limitations and may not be able to confer comprehensive protection to AI based technologies. In this scenario, alternative legal instruments may be explored to seek protection. Standalone algorithms and computer software per se can be protected under the copyrights act. In the same vein, due to the uncertainty related to the inventorship as well as non-patentable subject matter issues associated with the AI generated inventions, such an invention may be maintained as a trade secret.

Privacy issues

Technologies based on AI principally use large datasets for reiterative machine learning and pattern recognition. In case of medical or health care technologies, the databases comprise patient health related data, data related to biomarkers, genomics or DNA data. In India, personal data protection bill, 2018 and the DNA based technology (use and regulation) bill, 2017 have also been proposed. Thus, as and when these are legislated, due legal consideration with respect to the use of AI in personalized medicine would also be required.

Conclusion

AI is all set to usher in a new chapter in the life sciences and biotechnology sector. Despite the legal and ethical ambiguity discussed, reliance on AI to change the future of personalized medicine, genomics and bioinformatics appears almost inevitable.

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