IAM

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Key issues for senior life sciences executives

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What AI means for the life sciences space

LexOrbis

Manisha Singh and Shikha Singh

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Authors
Manisha Singh and Shikha Singh

LexOrbis INTELLECTUAL PROPERTY ATTORNEYS

709–710 Tolstoy House ,15–17 Tolstoy Marg, New Delhi 110001, India
Tel: +91 11 2371 6565
www.lexorbis.com

Introduction

In this article, the impact of AI on the life sciences field will be discussed, which broadly covers the pharmaceutical, medical and agricultural industries. This article also discusses the importance of AI in the development and improvement of these industries. In addition, the authors have tried to throw some light on the challenges faced by life sciences-based companies to get patent protection for their AI-based inventions.

A 2019 report from the World Intellectual Property Organization stated that AI emerged in the 1950s, with the first mention of the term appearing during the Dartmouth Summer Research Project on Artificial Intelligence in 1956. Generative AI (a type of artificial intelligence technology that can produce various types of content, including text, imagery, audio and synthetic data) tools have led to the invention of things such as virtual assistants, self-driving cars, smart homes, chatbots and surgical bots. We understand that AI is a computer science field that covers a wide range of areas intended to improve the ability of machines to make data-driven decisions and accurate predictions of events. By setting up sophisticated AI tools, an enormous amount of unstructured data consisting of text, images and sounds can be comprehended in a faster and

more efficient manner. In many scientific fields, AI is being increasingly considered and integrated. For instance, the most popular and commonly used OpenAI tool ChatGPT has become prominent in our daily lives in a short span of time. With the maturation and advancement of AI, it is set to have a significant impact on the life sciences industry. In combination with other tools such as machine learning (ML) and natural language processing, which make it possible for the algorithms to learn from experiences, AI and ML will help life sciences companies in different fields provide faster solutions in a cost-effective manner and with better public reach. The development of AI-based tools, particularly machines using AI, are helping industries to achieve commercials gains and are also contributing to the creation and management of their intellectual property rights portfolio.

Pharmaceutical industry

AI has certainly paved the way in the pharmaceutical industry owing to the availability of enormous amounts of data related to clinical trials and patients in general. It has been an important tool in revolutionising drug discovery and development, clinical trials and other critical activities. According to GlobalData's thematic research report, 'Artificial Intelligence in Drug Discovery', leading companies that have included AI in their business activities are AstraZeneca, Takeda, Pfizer, Sanofi, Novartis, Roche, Johnson & Johnson, GSK, Merck & Co, Bristol Myers Squibb, Bayer, Lilly, Merck and Astellas Pharma.

Drug discovery and development

In wake of the introduction of AI-related technologies, it is now common for pharmaceutical companies to leverage these technologies for maximum gain (eg, fast-tracking drug discovery and thereby reducing the cost involved). In the beginning of 2020, the British start-up Exscientia and the Japanese pharmaceutical firm Sumitomo Dainippon Pharma used AI to develop a drug for OCD. Typical drug development processed usually take around five years to reach the trial stage, but this drug took only a year; AI reduced the drug development time to a fifth of what is typical.

A few examples of AI tools include:

- DeepChem: it is an open-source deep learning framework for drug discovery. The Python-based framework offers a set of functionalities for applying deep learning in drug discovery. It uses Google TensorFlow and scikit-learn to build neural networks for deep learning.
- ODDT: the Open Drug Discovery Toolkit is an open-source tool for computer-aided drug discovery.
- ChatPandaGPT: this is a chat functionality, which has been integrated with the algorithm-based platform PandaOmics developed by Insilico Medicine Canada for targeted drug discovery. This functionality allows the user to query a knowledge graph (obtained by the platform) and identify the relationships between the data provided. ChatPandaGPT makes the knowledge graph more accessible and user-friendly, and it makes the information more understandable as well.

Clinical trials

Owing to the pandemic and the revolution in digital sciences at the same time, the ways in which clinical trials are being designed and conducted earlier are gradually transforming. In particular, the important components of the clinical trial process, such as study monitoring and patient enrolment, are benefiting from these transformations. AI algorithms, combined with effective digital infrastructure, could enable a continuous stream of clinical trial data to be cleaned, aggregated, coded, stored and managed. In addition, improved electronic data capture could also reduce the impact of human error in data collection and facilitate seamless integration with other databases. The same has been depicted in Figure 1.

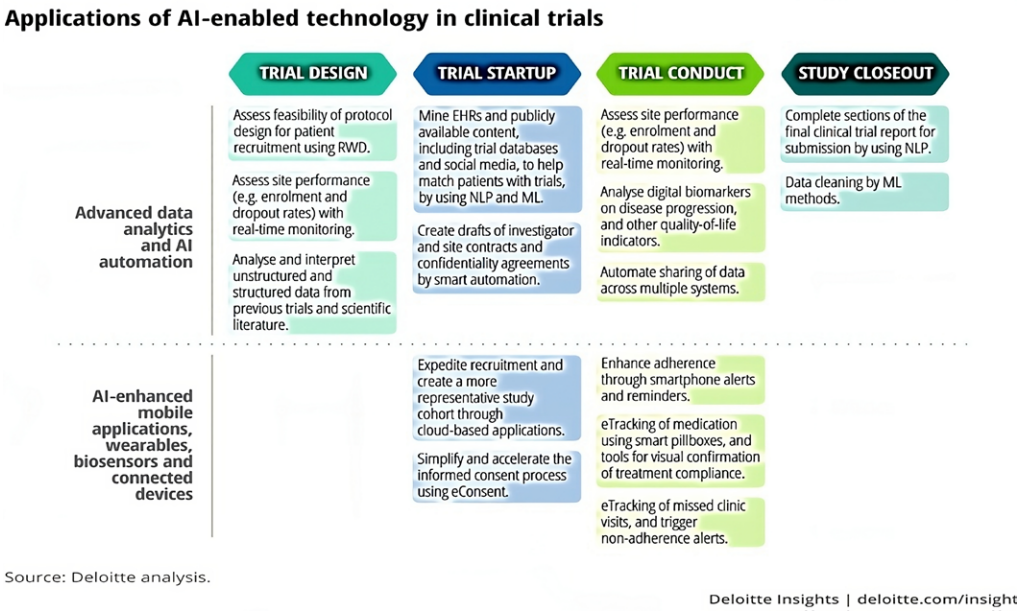

Figure 1. Applications of AI-enabled technology in clinical trials

Therefore, the adoption of AI technologies is becoming a critical business imperative, specifically for life science-based companies.

Supply chain

Drug manufacturers and pharmaceutical companies are transforming their businesses through AI. For instance, AI makes it easier to forecast demands and subsequently scale production on a needs basis. It also monitors in-line manufacturing processes to ensure the safety and quality of drugs. These interventions will certainly give life sciences companies confidence that their manufacturing processes are operating at a high standard and not putting the organisation in breach of regulations. Importantly, the bottlenecks caused by the pandemic tested the resiliency of the entire supply chain ecosystem. In a report issued by Deloitte, are five critical areas and processes of the biopharma supply chain have been identified where AI is likely to have the highest impact.

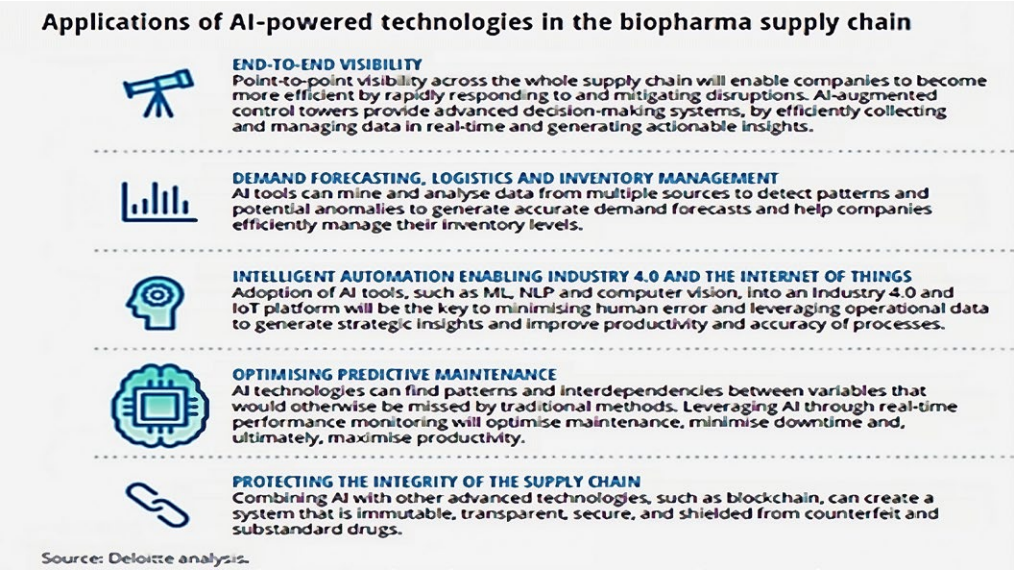

Figure 2. Applications of AI-powered technologies in the biopharma supply chain

Commercial and regulatory processes

Nowadays, reviewing promotional content for compliance purposes is a necessary, yet limiting, stage for any pharma or biopharma company. The current medical, legal and regulatory review processes for approving product marketing materials are uncomfortably relaxed and might be inconsistent, leading to repetitive cycle times. AI and ML have proven to significantly reduce the medical, legal and regulatory review time, while improving the accuracy of the content. This approach will certainly improve the speed and reliability of the processes, enabling therapies to get to market quicker.

Producing personalised medicine

Usually, while producing a drug or pharmaceutical product, the 'one size fits all' approach is applied in terms of medicine dosing. Little information about an individual patient is considered when a therapy is designed or a dosage is set. By continuously monitoring several parameters, AI may enable medical practitioners to adjust the dose size or, if the disease condition varies by, say, mutation, then the therapy can be revised and a more effective alternative can be developed. In this respect, the software company Enlitic specialises in developing deep learning medical tools that analyse unstructured records (medical history, images, blood tests, electrocardiograms and genome reports), helping doctors cater to the patient's real-time needs.

Accessibility of therapies and drugs

In the past, more than a decade and billions of dollars were needed to introduce a new drug to the market earlier. However, now with the help of AI, data can be accumulated and obtained from myriad sources (hospitals and research labs) in a compatible format. Besides this, AI can also help develop better healthcare networks and protocols, speeding up their introduction to the market at a reasonable price.

Medical industry

In this industry, with the advancement of biomedical technologies, a lot of exciting and encouraging developments have been witnessed in past few years, which are now reaching a peak. Medical devices incorporating AI hold the promise of revolutionising the healthcare industry, helping medical professionals more accurately and effectively diagnose and treat their patients and improve their overall care.

As technology advances, medical device companies are developing AI medical devices that serve the following three main functions:

- Chronic disease management: medical devices with AI could monitor patients and deliver treatment or medication as needed. For instance, diabetes patients could wear sensors to monitor their blood sugar levels and administer insulin to regulate them.
- Medical imaging: companies are developing medical devices with AI to conduct medical imaging with better image quality and clarity. These devices would also reduce a patient's exposure to radiation.
- IoT: the Internet of Things for medical devices is a system of wireless, interrelated and connected digital devices used by medical professionals to manage data, keep patients informed, reduce costs, monitor patients and work more effectively and efficiently. Companies are using the IoT in collaboration with medical devices with AI to improve patient outcomes. For example, the use of AI in telehealth has allowed for the creation of AI chatbots, which can review a patient's symptoms and suggest next steps, such as an in-person follow-up where necessary.

Diagnostics

AI and ML are effective at identifying characteristics in images that cannot be perceived by the human brain. Incomplete medical records and many cases can lead to erroneous predictions and disease diagnosis. Buoy Health is an AI-based chatbot that listens to the patient's health issues and associated symptoms, and then uses algorithms to guide the patient to the correct therapy. In addition, current diagnostics processes rely on either invasive techniques or gaining insights from radiological images. These include data from CT scans, X-rays and MRI machines. AI-based radiology tools will enable the clinicians to develop a more precise and detailed understanding of how a disease progresses by performing virtual biopsies.

Surgery

Nowadays, surgeries can be performed in previously inaccessible places using the da Vinci Surgical System. Once trained, the System will be competent enough to perform operations 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 to human performance, which predictably declines the longer the surgery is. This shows that AI, when employed appropriately in this domain of the life sciences sector, can create wonders.

Expanding healthcare access in developing regions

AI has enabled access to life-saving care in regions where trained professionals, such as radiologists or ultrasound technicians, are unavailable or rare. 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 these regions. Further, the healthcare start-up WeDoctor, independently conducts 11 diagnostic tests and uploads data for consultation in an automated fashion.

Agricultural industry

Owning to the advancement of AI, the agriculture industry is entering a whole new phase of evolution. Some new tools include the VineScout robot, Airavat 10 (Skylink Aero's drone with 10 litre capacity) and Airavat 20 (Skylink Aero's drone with 20 litre capacity). These can help with: leveraging computer vision technology for crop and soil monitoring; disease detection and predictive analytics; implementing AI based technologies for livestock health monitoring, intelligent spraying, automatic weeding, aerial survey and imaging, produce grading and sorting.

Patenting challenges of AI-based inventions in the life sciences industry

Owing to the lack of clarity in patent law for AI-driven innovations, companies may face difficulties in patenting their inventions. For instance, patent applications that use AI may face patent eligibility challenges as a result of unpatentable subject matter. From an Indian patent perspective, it may fall within the preclusion of Section 3(k) of the Indian Patents Act 1970. Further, AI-based inventions also raise considerable issues for inventorship. Most countries have laws that stipulate that inventors must be human. In those countries, AI cannot be an inventor. In the United States, the Federal Circuit recently heard arguments regarding whether the term 'inventor' in the Patent Act is broad enough to include AI. A recent ruling in Germany held that AI cannot be an inventor, but states that the owners of AI can name themselves as the inventors on the patent application (*DABUS* case). In this respect, India takes a similar approach to the corresponding Indian application of the AI-generated invention (DABUS) (patent application number 202017019068) in a similar objection pertaining to the inventorship raised by the Indian Patent Office.

However, the novel and inventive products or processes implementing AI would not face these above-mentioned challenges as such tools and approaches will be considered patent eligible subject matter in various jurisdictions.

Conclusion

In view of the comprehensive discussion in this article, we consider AI as a boosting agent for the life sciences industry. Not only will AI improve the functioning of these industries but it will also help them to protect themselves from any pitfalls faced in future. With respect to patent filings, different sectors have witnessed different trends. For instance, in 2022, the medical sector observed a decrease in number of patent filings in the initial quarter of 2022; there were 425 application by the month end of June 2022 vesus 458 patent application at

the same time in 2021 (data source is GlobalData). However, the patents granted for AI-based inventions followed a different pattern and grew from 91 over the three months ending June 2021 to 118 in the same period in 2022 (data source is GlobalData). Hence, generalisation in terms of predicting trends in patent filing is a challenging task in this area of discussion.

Manisha Singh

Founding partner
manisha@lexorbis.com

Manisha Singh is known and respected for her expertise in the prosecution and enforcement of all forms of IP rights and for strategising and managing the global patents, trademarks and design portfolios of large global and domestic companies.

She is extensively involved in IP litigation, with a focus on patent litigation covering all technical fields, particularly pharmaceuticals, telecommunications and mechanics.

She is an active member of many associations, such as INTA, APAA, AIPLA, AIPPI, LES and FICPI, and is actively involved in their committee work. She is an active writer and regularly authors articles and commentaries for some of the top IP publications.

Shikha Singh

Managing associate
shikha@lexorbis.com

Shikha Singh is a qualified biotechnologist with bachelor's degrees in technology and in law. She is a registered Indian patent agent with the government of India and has more than eight years of experience in IP.

Her primary roles are providing opinions to clients on complex and contentious issues related to the patentability of an invention, and searching, drafting, filing and prosecuting national and international patent applications. She deals with patent applications related to biological sciences, pharmaceuticals, biomedical engineering, nanotechnology, immunology, neutraceuticals, bioinformatics, bioprocess engineering, polymer technology, organic and inorganic chemistry, biochemicals, peptide chemistry, medicinal chemistry, organometallic chemistry, food technology and oil and gas chemistry. Shikha frequently appears before the Indian Patent Office and the Delhi High Court for various matters.