Trends of Blockchain in life sciences

Manisha Singh and Shikha Singh, of LexOrbis, provide an informative breakdown of the use of blockchain in the pharmaceutical, medical, and genomics industries.

Since the dawn of "Blockchain", also referred to as Distributed Ledger Technology or DLT, many researchers and industry experts have studied and speculated its potential in various industries like Fintech, Real Estates, Healthcare, Insurance Sector etc. This technology has and is continuing to gain traction across the globe due to its immutable, reliable, secured, efficient and federated features[1-2]. Also, the Indian Government organizations, such as Ministry of Commerce & Industry, Department for Promotion of Industry, and Internal Trade and Indian Patent Office, has identified its potentials and preferred availing the benefits of this technology including other artificial intelligence (AI) based technologies[3-4].

We, in this article, will explore the emerging trends in applications of Blockchain in various disciplines of Lifesciences and examine the challenges which might be faced in securing Intellectual Property Rights (IPRs) protection in India.

First, let's learn some basics about Blockchain

What it is?

Blockchain is a shared (decentralized), encrypted, immutable, distributed ledger technology which offers non-repudiation of transactions that can work with the absence of a trusted intermediary across a peer-to-peer, distributed network. In simpler words, Blockchain is a technology that allows computers (so- called nodes) to share information and exchange assets without the need of a centralized intermediary.

It has the following basic features:

A Chain of Blocks:

Blockchains are largely a sequential chain of small boxes (blocks) of code that includes cryptographically protected data. Each block on the chain includes a reference to the block that was added to the chain before it and each block contains specific information such as a financial transaction or other information based on the purpose of the chain. Once a block is added to the chain by the participants (users) it is nearly impossible to mutate it (immutable).

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Smart Contracts:

Smart contracts establish "how" the blockchain nodes work with each other. Smart contracts are a small amount of code that establish rules that the network of nodes follow and enforce through consensus-based majority before any transaction can be accepted onto the blockchain network.

Classification/types:

The blockchain technology has evolved since the year of its inception and hence different types of blockchain technology now exist in the industry. There are mainly four types of Blockchain Technologies namely Public, Private, Hybrid and Federated[5].

Public Blockchain: This kind of network is open to public and anyone interested to participate in the transaction can get involved.

Private Blockchain: A narrower form of Public Blockchain is Private Blockchain. They are ideal for using at a privately held company or organization that wants to use it for internal use-cases.

Hybrid Blockchain: Hybrid blockchain is a combination of a private and public blockchain.

Federated Blockchain:

A Federated blockchain (also known as consortium blockchains) is an innovative approach to solving organizations' needs where such organisations require both public and private blockchain features. In a Federated blockchain, some aspects of the organizations are made public, while others remain private. Unlike private blockchain, this type of blockchain technology still holds a decentralized nature.

Considering that most of the companies want the data to be kept secret and protected from their competitors, private blockchain platform seems more prudent to such use cases.

The term "transactions" used herein include money transaction, transaction related to data etc. In the case of life sciences/healthcare industry, it can be data in supply chain, clinical results data, research data etc.

Figure 1 above represents working of Blockchain in a simple manner:

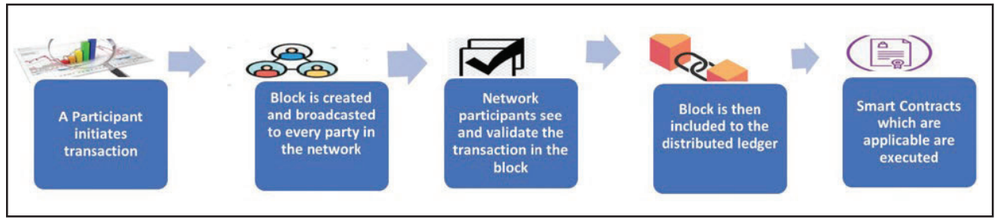


Figure 1

Applications in Life Sciences

Lifesciences is a broad field of sciences and includes biomedical, genomics, pharmaceuticals, and many more related branches of sciences.

Biomedical Sector:

This Sector finds ample consumption of blockchain technology. For instance, medical devices which collect, store, and transmit patient-specific data may utilize this technology to protect such information. It is likely that the data may be hacked from the device or captured during transmission, as is the case in every situation where data is centrally stored and transmitted to another central data store. We cannot dare to imagine that what would happen if a pacemaker or even medical equipment at a hospital during a surgery is hacked. The thought of the result is in itself very terrifying. And it could even be amplified by the increasing speed of technologies like 5G, 6G etc., that are going to transform health-care with the raise of technologies for instance remote surgeries etc., if not adequately safeguarded. The alternative is provided by Blockchain, whereby the data/information is cryptographically protected, immutable and private. Said advantages cannot be provided by traditional data storage and transmission processes.

With this technology precautionary upkeep of medical devices could be made easy. The technology enables the machines/devices to share their operating data with those responsible for maintaining it without violating regulatory issues.

This technology can be utilized to keep permanent records of the design, development, production, and distribution of medical devices as well as all the parts from suppliers. Once the information is submitted to a blockchain it cannot be changed, resulting in permanent traceability for every device. That is contributing to well managed provenance[5] record.

Lately, it was in the news that hospitals in Switzerland have trialled orders of medical devices via Blockchain and were successfully processed[6]. It was reported in the news that with co-operative approach of four hospitals, two suppliers and a software service provider it is possible to trace the route taken by a medical device and hence authenticate its efficiency.

1 Blockchain: A Catalyst for the Next Wave of Progress in Life Sciences- Cognizant;

2 Carly Guenther et.al.- Accenture life sciences

3 E-Request for EXPRESSION OF INTEREST (EOI) for Making use of Artificial Intelligence, Blockchain, IoT and other latest technologies in Patent Processing system of IPO No. IPO/POD/EOI/2018/1 Dated: 02/08/2018.

4 B.P.Singh et.al. -Blockchain Technology and Intellectual Property Rights, JIPR, 2019

5 Provenance refers to the ability to trace origin and confirm the authenticity of the object/article/device being traded.

6 https://www.med-technews.com/news/hospitals-trial-blockchain-tracking-of-medical-devices/

Résumés

Manisha Singh, founder and Managing Partner of LexOrbis

Manisha overviews and supervises all practice groups at the firm. Starting her career at the time when Indian IP laws and practices were undergoing substantial changes pursuant to India's obligations to comply with the TRIPS agreement, Manisha played an important and crucial role in advising and apprising Indian policy and law makers on global standards associated with IP administrative and enforcement systems. Manisha is known and respected for her deep expertise on prosecution and enforcement of all forms of IP rights and for strategizing and managing global patents, trademarks, and designs portfolios of large global and domestic companies. Her keen interest in using and deploying latest technology tools and processes has immensely helped the firm to develop efficient IP service delivery models and to provide best-in-the-class services. She is also known for her sharp litigation and negotiation skills for both IP and non-IP litigations and dispute resolution. She represents the Reserve Bank of India, India's central banking institution before the High Court of Delhi and the Supreme Court of India in cases related to banking and non-banking financial companies in addition to a large number of intellectual property litigations with a focus on patent litigations covering all technical fields – particularly pharmaceuticals, telecommunications, and mechanics. She has been involved and successfully resolved various trademarks, copyright and design infringement and passing off cases in shortest possible time and in most cost-efficient manner applying out-of-box strategies and thinking.

Shikha Singh, a Managing Associate at LexOrbis

Shikha is an advocate registered with the Bar Council of India, as well as a patent agent. She has a professional degree in Biotechnology. She regularly advises clients on IP strategy and portfolio management. Ms. Singh has in-depth knowledge of patent law and regulatory framework and extensive experience in patent filing, drafting, prosecution and advisory matters – especially in the biotechnology, nanotechnology, biopharmaceuticals, immunology, polymer sciences, chemical, pharmaceutical and start-up fields. She has delivered talks at various forums on patent law practice.

The parties involved were the Cantonal Hospital Winterthur, the Cantonal Hospital Baden, the University Children's Hospital Zurich and the Spitalregion Fürstenland Toggenburg, Anandic System Medical, ITRIS Medical and Xatena AG. This project was conducted as a trial.

Pharmaceutical Sector

The importance of blockchain in pharmaceutical industries is majorly for drug discovery, records management, provenance, handling patient sensitive data, disintermediation, and internal process management[1].

The technology finds its use in each of the above-mentioned use cases. The major advantages which one may speculate from implementation of such technology is reduction in counterfeited drugs, timely auditing and streaming of the non-valid batches, obviating regulatory delay, ensuring reputation in market, and most importantly saving lives.

Big Pharma companies like Pfizer, Amgen and Sanofi are working to leverage to blockchain technology. Use cases range from storing patient health data safely, to speeding up clinical trials, and ultimately lowering drug development costs.

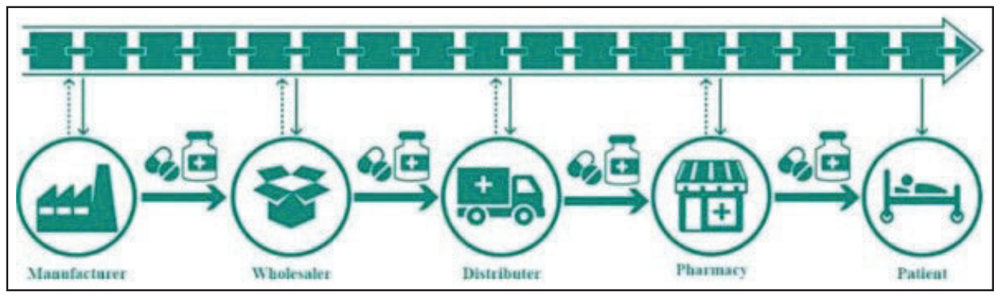
Gladly, as per recent piece in the Indian Express[7] on March 12, 2021, it has been reported that state and central government hospitals may be able to get an assurance of the authenticity and quality of medicines procured in bulk using the Government e-Marketplace (GeM), as GeM aims to use blockchain technology in ensuring traceability of these medicines from the point of supply to their final destination.

A brief representation of how blockchain works in pharma industry is provided in Figure 2[8].

Genomics:

The researchers/scientists and scientific institutes are also leveraging Blockchain technology for enhancing resource-sharing (both computation and storage), facilitate decentralized data distribution, promote collaborative work, and provide genome privacy[9].

Figure 2



> **Once a block is added to the chain by the participants (users) it is nearly impossible to mutate it.**

7 https://indianexpress.com/article/business/drug-procurement-via-blockchain-at-govt-hospitals-in-one-year-7224433/

8 Ijazul Haq et. al. , 2018

9 "Realizing the potential of blockchain technologies in genomics Halil Ibrahim Ozercan,1 Atalay Mert Ileri,2 Erman Ayday,1 and Can Alkan1 1Department of Computer Engineering, Bilkent University, Ankara 06800, Turkey; 2Department of Electrical Engineering and Computer Science, Massachusetts Institute of Technology, Cambridge, Massachusetts 02139, USA.

10 https://www.thehindubusinessline.com/news/indian-israeli-firms-in-blockchain-tech-tie-up-for-genetics/article24622745.ece

11 https://ipindia.gov.in/writereaddata/Portal/IPOAct/1_31_1_patent-act-1970-11march2015.pdf

Genomic drugs open the world of genetic data for providing an apposite diagnosis, prognosis, and appropriate treatment of several genetic diseases. Using genetic engineering/genomic techniques, an individual's genetic information is profiled to determine their susceptibility to a disease and appropriate treatment options for their personalized medicine. However, the increase in genetic data also comes with some problems such as data storage/management, access, security, and privacy. Blockchain comes here for rescue in a similar way as described supra.

By genomic mapping, scientists/researchers can gain a better understanding of the mechanisms involved in thousands of these rare diseases and common medical conditions. Poor access and non-interplay of such data has always been and continues to be, a problem in healthcare.

Sometimes, genomic data does not have a clearly identified owner, rendering such information susceptible to random sharing, creating privacy issues for the actual owner. This large volume of available genetic data, in the absence of strong systems for security and authentication, poses genuine concerns which can be addressed by the blockchain technology.

In the year 2018, Mapmygenome, an Indian based molecular diagnostics company has tied up with Digital DNAtix Ltd, an Israel-based blockchain genetics company to give a fillip to the way people can use their personal genome data in healthcare[10].

Intellectual Property Rights safeguards such innovative technology and hence enhance development and evolution of the same.

Patent filing trends:

India:

As per an Article dated May 17, 20194, it was shown that nearly 112 patent applications were published till that date and contribution of Indian applicants was approximately 39 in number. Guessing that most of the application were filed in the field of electronics/computer sciences, it seems a decent number. However, scope of improvement certainly exists in terms of increase in number of patent applications related to

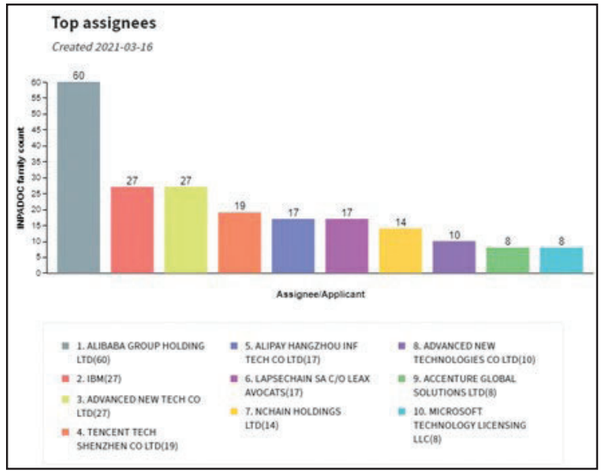


Figure 3

Blockchain technology in general and Blockchain based medical devices.

Worldwide:

A basic search conducted on Derwent Innovation reveals that most of the blockchain related patent applications are filed by Alibaba Group Holding Ltd. followed by IBM, Accenture, Microsoft etc.

The graph in Figure 3 depicts top filers in the domain of blockchain technology:

In a simple search on World Intellectual Property Organisation (WIPO) Portal related to blockchain based inventions in Genomics and Medical devices, it was noticed that China and US are major filers.

Figure 4 represents data of blockchain based patent applications filed in the field of genomics.

Figure 5 represent data of blockchain based patent applications filed in the field of medical devices.

The above indicates that Indian applicants need to focus on this area of technology for obtaining patents so that contribution of India towards providing Patent Protection can be acknowledged globally.

Patentability of blockchain related invention in India:

Since it is basically an algorithm, Blockchain technology will face challenge pertaining to Section 3 (k) of the Patents Act, 1970[11w], if claimed as lone. However, if it is worked with a hardware then such system is patent eligible subject matter in India. Based on similar concept, medical device which will be based on

Figure 4

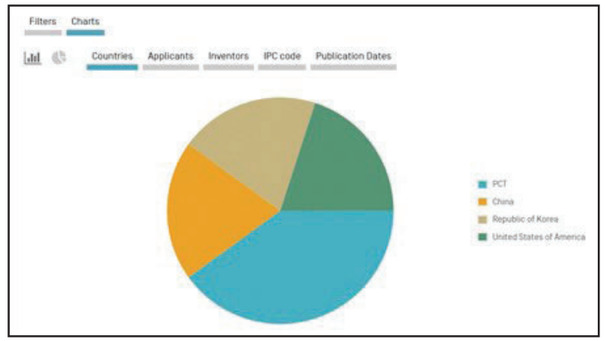
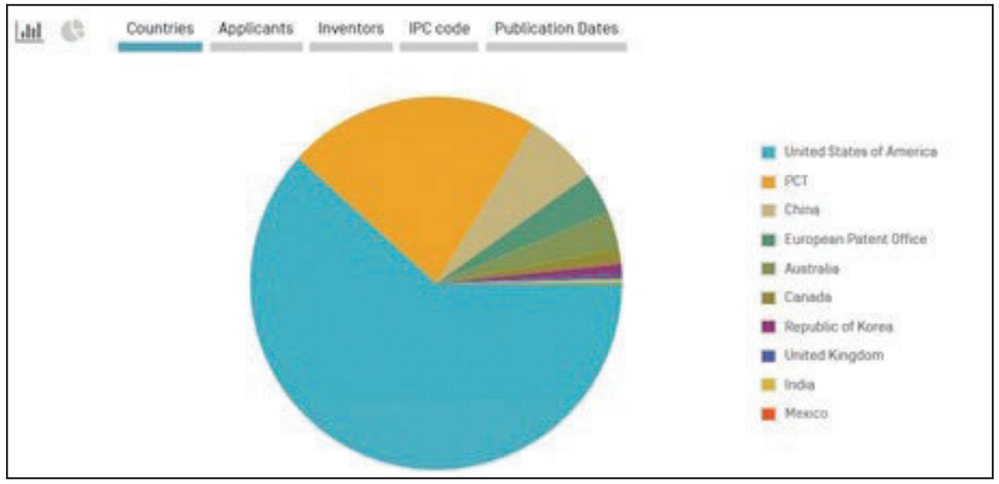


Figure 5



Blockchain technology will be considered patentable. In any event grant of patent protection will depend on qualification of other patentability criteria such as novelty, inventive step and industrial applicability.

Method of identifying biomarkers related to a rare disease utilizing blockchain based genomic tools and developing a drug for treatment of the same can be considered patentable. However, there are possibilities that such subject matter may be objected under Section 3 (i) of the Patents Act, 197010, which precludes from patentability method of treatment. This issue can be delt with on a case-by-case basis.

The Takeaway:
Blockchain technology is gradually increasing hold in pharmaceutical, medical, and genomics industries it maybe that soon all industries will be utilizing blockchain for various use cases. It is observed that inclusion of such technology is embraced by not only enterprises but Indian Government bodies as well. Though we have some good news with respect to utilization of blockchain in drug procurement by the Indian Hospitals (mentioned above). However, as attempted by Hospitals in Switzerland (informed supra), we hope that Indian Hospitals will also adopt blockchain technology for monitoring medical devices for the improved and efficient treatment.

> **The thought of the result is in itself very terrifying.**

Graphics as supplied by authors

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