

The Patent Lawyer

GLOBAL REACH, LOCAL KNOWLEDGE

www.patentlawyermagazine.com

September /
October 2022



Discussion on Chinese service invention-creation and rights ownership thereof

Zhongling HAN and Xiaodong WANG of Beijing Sanyou Intellectual Property Agency Ltd. offer advice for determining an “Employer-First” and “Employee-First” dual model as a solution for invention-creation ownership.

An interview with GE

Page 12



New Canadian rules

Page 16



Adaption of the description

Page 21



BIG Data unveiling BIGGER opportunities for life sciences ecosystem & innovation

Manisha Singh, Founder Partner, and Neha Ruleha, Senior Associate, of LexOrbis review the prospects that Big Data is offering to the industry and the IPR regulation that innovators should monitor.

Sherlock Holmes' classical quote: "Data! Data! Data! I can't make bricks without clay" conveys the inevitability of minute details and logic for solving a mystery. In the similar vein, modern-day Big Data holds the key to unlocking the doors of latent patterns in the real world of the digital era.

Big Data, since its advent, has become a fascinating buzzword for academia, governments, and several businesses, e.g., Industry, telecom, finance, insurance, and the healthcare sector. Put simply, Big Data refers to huge, diverse, rapidly growing information which may be used for drawing valuable inferences. It is said that nearly 90% of the global data was generated over the last two years alone. The exponential trend of data is being triggered by the growth of the Internet of Things (IoT). Coupled with the power of artificial intelligence, Big Data applications pour into the realm of innovation too.

Industries and startups are keen to tap into the potential of the complex web of interlinked information and enormous data being generated every second in life science verticals, be it, pharmaceuticals, biotechnology, healthcare, or MedTech. Big Data holds great promise in this regard. This optimism is reflected in rising investments and also supported by various outlook studies.^{1,2}

In this article, we will explore emerging trends and applications of Big Data Intelligence in the life sciences ecosystem and present glimpses of opportunities that Big Data offers in innovations along with the challenges it faces, particularly in the Indian Intellectual Property Rights (IPR) regime.



Manisha Singh



Neha Ruleha

'101' of Big Data – the basics

Wider connotation

'Big Data' is an umbrella term that describes increasing streams of data, as well as advanced approaches and techniques being used to gain valuable insights from this voluminous data.

The five Vs of Big Data

Rather than defining formally, most literature characterize Big Data in terms of five V attributes seriatim:

Volume: The phrase 'Big' suggests that a huge amount of data is a *sine qua non*. Its size is too large and complex to be dealt with using the traditional approach. Think of large-scale data in genomics, patient data which runs into millions of past records and are continuously added.

Variety: It refers to diverse data sets from various sources. It could be conventional structured data arrayed in row-column and semi-structured or unstructured data such as text, image, audio, video, GIS, GPS, sensor, social media data etc. Advanced computing takes care of heterogeneity arising from the latter class. Think of collection of all prior-art literature, clinical trial data.

Velocity: It is the high speed at which streams of data are generated. It refers to how rapidly data moves. Big Data can deal with intricacies of near real-time processing so as to enable prompt business responses. Data flows from medical devices and sensors are to be tracked and tapped quickly and dynamically.

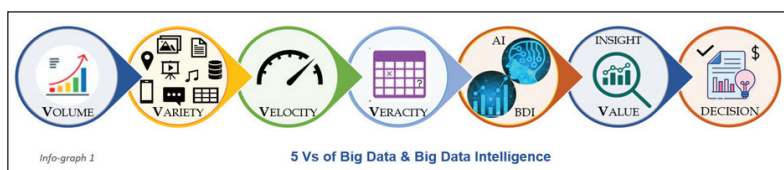
¹ World Intellectual Property Report 'The Direction of Innovation' (2022)

² Deloitte 'Global Life Sciences Outlook' (2019-2022)

While said three Vs are intrinsic features, the next two Vs are utilitarian in nature.

Veracity: It refers to quality and accuracy of collected or generated data. Generally, Big Data is messy, noisy, inconsistent, and even may have some bias. The incomplete data of a patient's medical history could be fatal at times. Multiple checks and data cleaning can be done beforehand, and missing points can be imputed suitably. The quality of output analytics and insights evidently rests upon the veracity of input data.

Value: The last V refers to potential value, which can be derived from Big Data insights. It is where innovation comes into play. Entities can use the same Big Data tools, but the way they utilize value from that data is unique to them. Innovative ideas when applied correctly may lead to data monetization and the 'right decision at right time'.



AI-driven Big Data analytics

Big Data (BD) and Artificial Intelligence (AI) are seemingly inseparable. AI 'mimics' real-world conditions. AI requires high-quality data, and the more data AI receives, the more accurate and efficient 'learning' we can expect. Big Data Intelligence (BDI) includes various algorithms and techniques such as Deep Learning, Machine Learning (ML), Predictive Modeling, Classification Algorithms, Natural Language Processing (NLP), Image Processing and is used to discover actionable insights, find new patterns, and unveil relationships in massive and diverse data.

Now, let us have a look at some practical aspects.

BDI applications in the life sciences ecosystem

Pharmaceutical & biomedical sector

Given the small patent window of 20 years and the lengthy, risky, and complex process of drug development, BDI enables pharmaceutical companies to accelerate the discovery process of new drugs in order to realize maximum return on investment and reduce R&D costs.

BDI also assists in enhanced and targeted recruiting of niche patients for clinical trials. A cost-effective, faster, and better clinical trial could be achieved by analyzing the participants' demographic and historical data, genomics, real-time remote patient monitoring (RMP) data, and reviewing past clinical trial events data.

Data mining of Adverse Drug Events (ADEs)

“
The global personalized medicine market is expected to increase at over 11% CAGR by 2024, with the aid of advances in healthcare analytics and AI.
”

along with data from healthcare service providers, pharma companies, regulators, and social media could lead to proactive pharmacovigilance and better drug safety surveillance and signals.

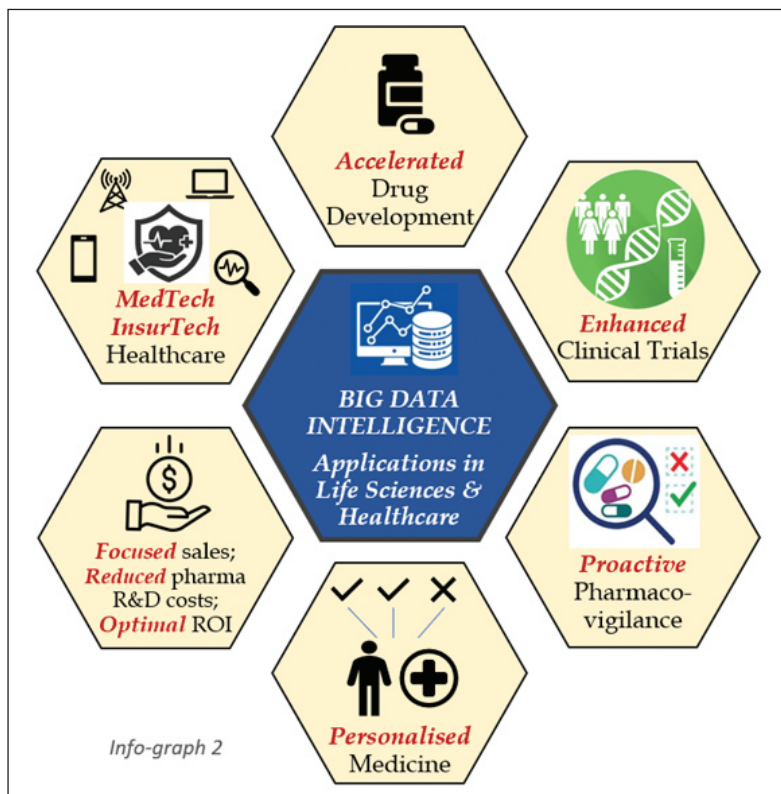
Résumés

Manisha Singh – Founder Partner, LexOrbis

Manisha Singh is the Founder Partner of LexOrbis. Manisha is known and respected for her deep expertise in prosecution and enforcement of all forms of IP rights and for strategizing and managing global patents, trademarks, and design portfolios of large global and domestic companies. Her keen interest in using and deploying the latest technology tools and processes has immensely helped the firm develop efficient IP service delivery models and 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 is involved in 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 in and successfully resolved various trademarks, copyright, design infringement, and passing off cases in the shortest possible time and the most cost-efficient manner applying out-of-box strategies and thinking.

Neha Ruleha, Senior Associate, LexOrbis

Neha is a registered patent agent and her proficiency ranges in life sciences, IP practice and law. She holds a master's degree in Biotechnology and earned research experience at the Indian Institute of Technology, Bombay. On a professional front, she deals with drafting, prosecution, opposition and advisory matters, especially in biotechnology, biomedical, pharmaceuticals, nanotechnology and polymer-related inventions. Ms. Ruhela has a profound understanding of patent laws and regulations and keeps herself abreast the latest trends in the sector.



UK-based MedChemica, specialized in Big Data cheminformatics, enables knowledge sharing without sharing partner organisations' intellectual property. It facilitates accelerated drug development by massive scale analysis of the relationships between chemical structures and biological properties. Novartis' Data42 program claims to bring transformational change in healthcare data and research. Pharma giants agreed to share historical cancer trial data through Project Data Sphere which leverages the power of pooled data for the discovery of new treatments.

National Brain Research Centre (NBRC) in India has developed an integrated BDI framework 'BHARAT' for early diagnostic biomarkers of Alzheimer's disease using brain imaging, metabolic, and neuropsychological scores.³

In contrast to the 'one-size-fits-all' medical approach, personalized medicine is perceived as 'the right treatment for the right person'. A huge amount of Electronic Medical Records (EMRs), genomic data, and clinical trial data are being analyzed to produce targeted medicine and spot new opportunities. Pfizer formulated XALKORI® (crizotinib), a precision medicine, which is used specifically to treat lung cancer patients with the ALK gene mutation. The global personalized medicine market is expected to increase at over 11% CAGR by 2024, with the aid of advances in healthcare analytics and AI.

Healthcare: MedTech & InsurTech

The Internet of Medical Things (IoMT), the connected infrastructure of medical devices, software

applications, and health systems and services, is transforming MedTech's role in healthcare. MedTech Intelligence is harnessing the power of BDI where innovations such as Digital Therapeutics (DTx), Wearables, Medical Devices, and Software-as-a-Medical Device (SaMD) are helping the healthcare industry.

Wearables technology through devices, sensors, and health-apps provide a vast amount of historical as well as real-time health, lifestyle, and activity data. BDI empowers InsurTechs, Life and Health Insurers to come up with innovative personalized insurance products based on evidence-based risk assessment and also extend incentives to 'healthy' customers, e.g., discount on the renewal premiums.⁴

The Indian Health Ministry has broadened the scope of 'medical devices' to accommodate and regulate SaMD. By bringing suitable changes in Medical Devices Rules, software or app used for diagnosis, prevention, monitoring or treatment has been classified as a medical device with effect from April 2020.⁵ AI-based analysis tools such as Automated Radiological Image Processing Software are now recognized as medical devices.

Interplay of BDI & IPR

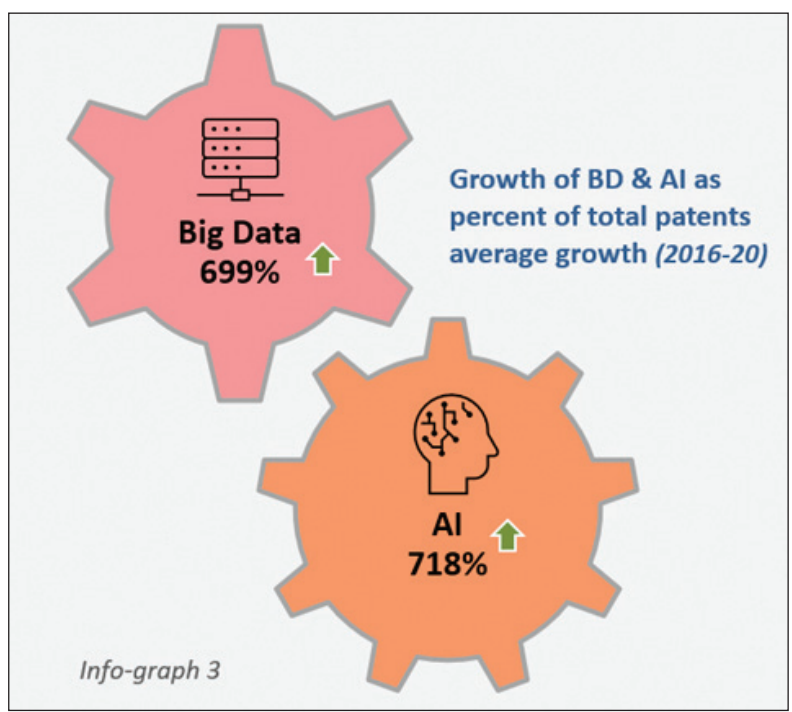
Global scenario

World Intellectual Property (WIPO) Report – 'The Direction of Innovation' (2022) reveals that AI and BD-related patents have each grown around eight times faster than all patents during 2016-2020 (see graph 3). China and the United States share the largest pie in BDI-related filings.

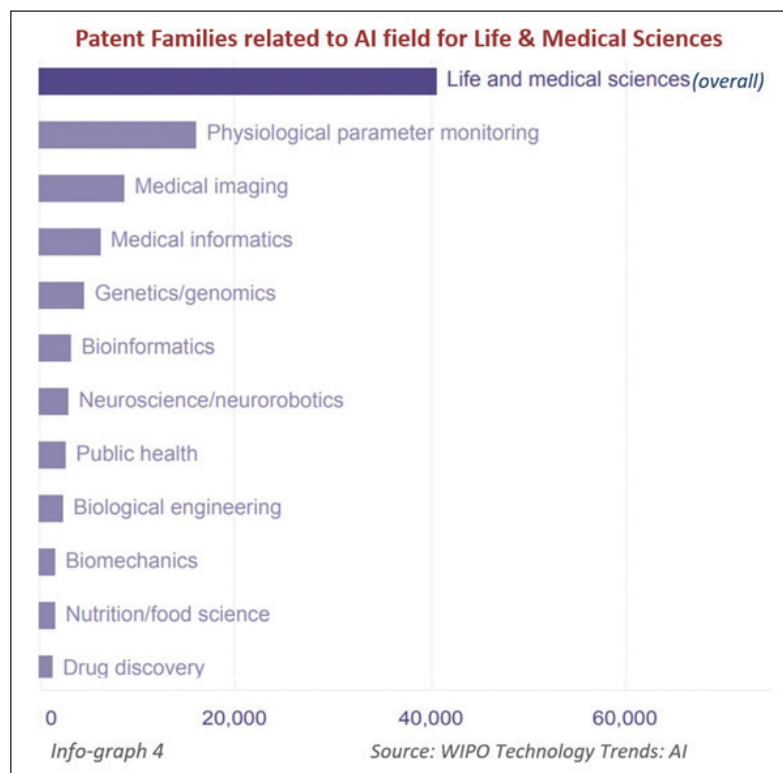
WIPO findings⁶ indicate that the top industries in the AI field are telecommunications (15% of all

³ <https://www.thehindubusinessline.com/news/science/big-data-may-help-get-new-clues-to-alzheimers/article26111803.ece>

⁴ <https://www.intel.in/content/www/in/en/financial-services-it/solutions/insurance-analytics-wearables.html>



AI-related patents), transportation (15%), and life & medical sciences (12%). The distribution of patent families related to AI applications for life & medical sciences can be seen in graph 4.

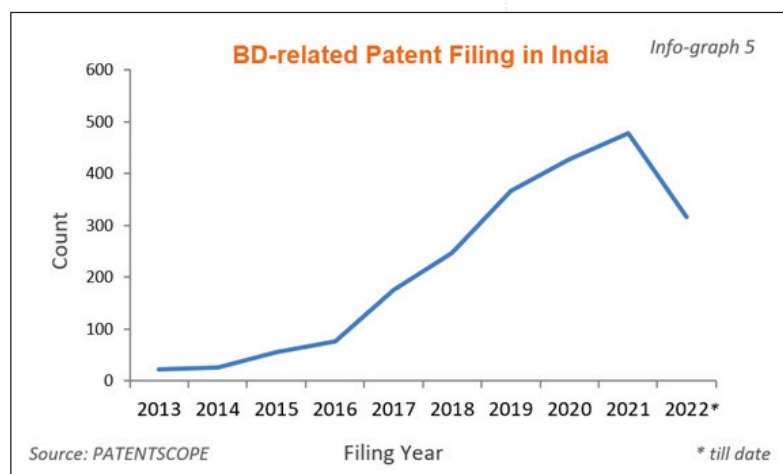


Indian context

PATENTSCOPE portal suggests filing of more than 2,200 BD-related patent documents under Indian jurisdiction so far. Graph 5 illustrates that the increasing trend of BD-related patent numbers (excluding the ongoing 2022 figure) is an aspiring one. A 2021-study⁷ mentions that the four largest categories for AI patents in India, in sequence, are personal devices and computing, business, telecommunications, and life sciences.

India is now home to more than 1900 AI, 570 BD Analytics, and 25 life sciences deep-tech startups are on the right track.⁸ That said, innovators in India still have scope for enhance-

- ⁵ Notification No. S.O. 648(E) dated 11-02-2020, Gazette of India
- ⁶ World Intellectual Property Report 'Technology Trends 2019 - Artificial Intelligence' (2019)
- ⁷ Center for Security and Emerging Technology (CSET) Paper 'Mapping India's AI Potential' (2021)
- ⁸ NASSCOM 'India's DeepTech Start-Ups - The Next Big Opportunity' (2022)
- ⁹ 2020 (81) PTC 489/Del (Ferid Allani vs Union of India)



ment so as to utilize the full potential of the BDI ecosystem, provided the issues they face are resolved properly.

Challenges

Patentability

BD-related patents, being based on AI applications and tools, suffer from Schrödinger's cat paradox – simultaneously both dead and alive. Standalone software or AI applications or computer program *per se* are hit by Section 3(k) of the Indian Patents Act and thus non-patentable. However, this statutory eclipse can be cured in light of Computer Related Inventions (CRIs) examination guidelines and settled judicial precedents.⁹ If a mathematical method or computer program or algorithm is associated with an invention along with some essential hardware or device, then such an invention might be patentable.

The lack of explicit mention or explanation of the term 'AI' or 'BD' in the Act and guidelines leads to ambiguity. The implied and net effect, in practice, would be that the protection of AI and BD-related innovations is subject to varied assessment and discretionary interpretation by Controllers in the Indian Patent Office.

Indian Parliamentary Standing Committee, in its 2021 Report¹⁰, also took cognizance of the inadequacy of existing IPR laws to facilitate emerging technologies such as AI, ML, & BDI and made recommendations accordingly.

Another hindrance lies in the prerequisite that the inventor should be a natural person, and AI or BD system cannot be considered as an inventor.

Privacy

As life sciences & allied industries hold treasures of highly sensitive and personal information, BDI environment needs to maintain a balance between innovations and data privacy by adopting fair practices and better compliances – a feasible *quid pro quo* between rights and responsibility. Informed consent, full data policy disclosure, prudent cross-border, and third-party data sharing are crucial to ensure in today's world.

Given the Indian Supreme Court's declaration of the fundamental right to privacy in 2017 and European Union's General Data Protection Regulation (GDPR) already in place; repeated delays in bringing safeguarding framework as was proposed under Indian Personal Data Protection Bill 2019, are disheartening.

'Big' way forward

Though the booming prospects of BD applications have set the tone for enthusiastic incubators, the life science analytics market is yet to be ripened by scaling up the size,

investment and coverage of products and services. At the same time, we consider the Government to act as an enabler and catalyst for the AI-BD ecosystem. Innovative policies, adaptive regulations, and favorable business climates will cherish the sentiments of all stakeholders.

With regards to legislative and policy response in India, we can expect an expeditious review of some time-worn IPR provisions in line with best global practices and a re-assessment of the National IPR Policy, 2016 so as to protect and foster innovations in emerging technologies. While re-shaping, the approach in linking the mathematical methods or algorithms to a tangible technical device (UK practice) or a practical application (US practice) as a process should be adopted in India to facilitate their patentability.¹⁰ Another possibility of creating a separate category of rights for AI and BD-related inventions is also gaining global traction.

After finalization of the proposed data protection law in India, a 'sandbox' initiative is likely to be launched for live testing of products or services in a relaxed regulatory environment to encourage innovators in AI, ML & BDI, particularly start-ups.¹¹

The government as the sole owner of public

service data may enforce 'Open Data' program more proactively. Through the digital platform Covid Vaccine Intelligence Network (COWIN), India's herculean immunization drive has administered more than two billion doses so far. This rich data-hub might help epidemiologists and the pharma sector attain unprecedented insights to combat future pandemics.

With the portrayal as sketched above; lastly, we foresee increasing demand for well-equipped IP professionals having techno-legal expertise with Big Data Intelligence portfolios.

¹⁰ Parliamentary Committee on Commerce Report 'Review of the Intellectual Property Rights Regime in India' (2021)

¹¹ Joint Parliamentary Committee's 'Report on Personal Data Protection Bill, 2019' (2021)

Contact

LexOrbis

709-710 Tolstoy House, 15-17 Tolstoy Marg, New Delhi – 110001, India

Tel: +91 2371 6565

mail@lexorbis.com

www.lexorbis.com

LexOrbis INTELLECTUAL PROPERTY ATTORNEYS

Your most
trusted
IP Partner

- » **IBLJ:** 2019 Indian Law Firm Awards, IP Protection
- » **WTR 1000:** 2019 Indian Law Firm Awards, IP Protection
- » **Managing Intellectual Property:** 2019, Tier 3, Trademark Prosecution
- » **Legal Era:** 2019 IP Star women of the year, Manisha Singh
- » **GIPC:** 2019 Award for Excellence for invaluable services in the field of IP to Manisha Singh
- » **IAM Patent 1000, 2018:** Recommended Law Firm - Patent Prosecution
- » **India Business Law Journal, 2018:** Manisha Singh recognized as one of India's Top 100 Lawyers, The A-List
- » **Asia Law Profile 2018:** Rated as Notable Firm, Asia Pacific Region
- » **Asialaw 2018:** Manisha Singh recognized as Leading Lawyer for IP
- » **Managing Intellectual Property, 2018:** Rated as a Tier 3 Firm in Patent Prosecution
- » **World Intellectual Property Forum:** 2018, Ranked and Awarded amongst the Top 10 most Prestigious & Trusted IP Law firms of India, 2018
- » **World HRD Congress:** 2018, ET NOW, Stars of the Industry Award for Excellence