# "Secure and Ethical Innovations: Patenting Ai Models for Precision Medicine, Personalized Treatment, and Drug Discovery in Healthcare"

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#### ABSTRACT

AI's prominence has surged in the digital economy's evolving landscape in the last decade, marking a transformative shift. This paper delves into the global race for AI development, examining the distinctive strategies adopted by countries and their evolution over time. The study uses worldwide patent data to identify countries specializing in AI technologies, analyse their efforts to attract foreign inventors and explore trends in specific AI techniques. The research introduces innovative indices, the National Breeding Ground (NBG) and the International Breeding Ground (IBG), shedding light on market favourability and cross-border patent protection. Comparing different strategies for identifying AI patents, the study employs a keyword-based approach and contrasts its results with those based on the International Patent Classification. The findings demonstrate the efficiency of the keyword-based method in capturing patents associated with the essence of AI, providing a high-quality dataset. The paper also delves into the fundamental distinction between software and ML, addressing challenges in proving the patentability of software innovations. The discussion extends to the patenting landscape in India, offering insights into the complexities of obtaining software patents and outlining strategies for drafting claims and specifications. Transitioning to the realm of ML, the paper defines ML and its subset, Deep Learning, emphasizing the programming of computers to learn from data. It navigates through examples of ML applications in chemistry, highlighting innovative patents that leverage ML for pathogen detection and regulatory molecule identification. The discussion extends to patentability considerations for European ML inventions, categorizing ML techniques based on their potential for technical solutions to technical problems. The paper offers a comprehensive overview of the global AI race, nuances in patent identification strategies, challenges in software patenting, and the patentability landscape for ML inventions, contributing valuable insights to the intersection of law, technology, and innovation.

Keywords: AI, Global AI Race, Patent Data, Software Patents, ML.

#### INTRODUCTION

For decades, businesses and societies throughout the world have been using information and communication technology to make the shift from an analog to digital economy. Artificial intelligence (AI) is a major step forward in the digitization movement. The recent decade has seen a surge in interest in artificial intelligence (AI) due to the widespread availability of large datasets and the development of high-performance parallel computing processors.AI may be integrated into many technologies, such as software, algorithms, processes, and robots. These technologies are capable of functioning well when equipped with the ability to anticipate and understand their surroundings.

Many governments widely recognise AI as a strategic technology because of its extensive reach and potential effects. Consequently, worldwide competition in AI emerged as governments began to allocate more resources towards creating national AI plans to acquire a competitive edge in global markets and industries. Nonetheless, according to innovation systems (IS) theory, technological progress may be influenced by unique national features, even if nations are pursuing similar goals. Technology and the knowledge it entail are not confined to the institutional framework of any one nation or area, and this fact is widely acknowledged. Most technologies, however, have a knowledge base that is not limited by any one country. Simultaneously, the inherent attributes of each technology type influence the development of their specific knowledge base and the spread of their practical implementations.<sup>i</sup>

Hence, we examine the following aspects over a period of time: i) the countries that have been focusing on and progressively embracing AI technologies; ii) nations who want to protect their AI-related intellectual property abroad or make their markets more attractive to global inventors and enterprises by enacting strong domestic protections for AI-related IP; and iii) the global trends we may deduce for individual AI methods. For this purpose, we apply a broad definition of an AI patent and access patent data from throughout the world. We also find patents that make use of AI approaches, such as complex statistical and mathematical models for enacting AI features like vision, language, and

decision-making, in addition to those that just mention AI. To compare countries' levels of technological development, we use standard measures of achievement. The NBI and IBG are also introduced. The first classifies countries according to market favourability, which measures how readily exploitable the market is seen to be by inventors and businesses. The second rating considers a country's ability to entice AI patent applications from foreign innovators or corporations, as well as how well AI patents filed in the country provide legal protection on a global scale.<sup>ii</sup> We have seen an increase in the number of nations that have developed expertise in AI during the last several decades, with a particularly significant expansion occurring mostly in the 1990s. However, the use of AI-related methods significantly increased around 2000, mostly driven by applying biological models such as neural networks, guided and unstructured ML, deep learning, etc. Regarding world leadership, there is evidence of a reduction in the significance of Japan and some European nations. At the same time, there is a notable growth in the importance of the United States and the advent of China. These two prominent nations approach AI research in various ways, which will be further discussed in the following sections.

#### **Comparison of Strategies for Identifying Ai Patents**

As previously stated, several options are available for patent searches on a certain subject, such as using keywords and patent categorization systems. Due to implementing a keyword-centric approach, we conducted a comparative analysis between our findings and those of two other AI-focused studies that use the International Patent Classification (IPC) codes. In short, every code used pertains to the subclass "Computer systems based on specific computational models" (G06 N) while also including codes related to the subclasses "Optical Computing Devices" (G06E) "Analogue Computers" (G06G), "Hybrid Computing Arrangements" (G06J), "Electric Digital Data Processing" (G06F), and one related to the subgroup of electric adaptive control systems (G05B 13/02). Eliminating utility models for comparison, the search resulted in 23,599 and 146,049 priority submissions, respectively.<sup>iii</sup>Manually selecting the first one hundred patents from our dataset that met two criteria—first, that they had a title and abstract, and second, that they were written in English—allowed us to compare the efficacy of our search methods to those of other researchers. The top one hundred items from each of the two competing datasets that met our criteria but were left out of our own were then selected. We were able to get 300 patents, all of which were properly filed away after being sorted by title and abstract.<sup>iv</sup> While our objective is not to get into an extensive debate over the definition of AI, we must provide a clear definition of an AI patent to facilitate this classification.

Consequently, we classified as linked to AI any patents that satisfied at least one of the following conditions, keeping in mind the overall picture of AI: i) It may be used to generate decisions, interpretations, and knowledge summaries that benefit from prediction or categorization; ii) It makes the patent's selection-improving actions and parameters amenable to automation and optimization; iii) It makes it easier to create data that can be analyzed or corrected on one's own; iv) It has to do with information-based instruction, learning, or dynamic adjustment; v) Meaningful things or patterns may be recognized and evaluated with its help. All of the data and R scripts used to achieve these findings are accessible in a public GitHub repository so that anybody may check or reproduce them. Thirteen of the sample patents did not contain enough data for us to clearly identify them, hence we classified them as "unclear." Figure 1 illustrates this contrast by drawing attention to the many commonalities between our query and Queries 2 and 3. It also demonstrates the accuracy of each query in determining whether or not a patent is related to AI, based on an analysis of 287 papers.<sup>v</sup>



Source: https://www.sciencedirect.com/science/article/pii/S0172219020300806#fig1.

Figure 1: Comparison of results between the selected queries.

Figure 1 shows that our research findings are similar to those of the two studies we compared them to. In particular, questions 2 and 3 may help us find an additional 28.2% and 33.1% of our findings. However, given the above description, those two searches are far less efficient at discovering AI patents. Specifically, including IPC codes that are less important to AI in Query 3 dramatically improves the number of returns. The fact that only 37.4 per cent of the patents in this collection are related to AI severely compromises the validity of the conclusions drawn from the analysis of this data. Compared to Query 2, ours is more precise (95.7% vs. 83.0%).<sup>vi</sup>

As a consequence, it produces a dataset that is comparable in size but much more refined. These findings might be explained by the fact that IP offices classify patents in accordance with their criteria, which could lead to important details of the invention being lost in translation to the standardized IPC language. The authors stress that researchers exploring applications across IP offices must pay special attention to computer technology since it is a technical topic.

Multiple categories may apply to the same patent application on this subject, and even when they do, various patent offices may assign different codes. Therefore, it is shown that employing a keyword-based search is preferable for overcoming the challenges experienced by other approaches to comprehend vast and ever-evolving technology like AI thoroughly. Specifically, utilizing AI-relevant keywords boosts the chance of locating patents explicitly tied to AI aims, thereby boosting the overall quality of the dataset.

## ML

ML is a specialized branch of AI. ML involves training a digital machine to exhibit learning behaviours similar to humans or animals. ML employs statistical methodologies to enable computer systems to "learn" from data and enhance their performance on a given job without explicit programming.<sup>vii</sup>

The method of ML often involves constructing a mathematical model using a certain collection of input training data and then using this model to make predictions or generate outputs based on a separate set of test data.

# **Deep Learning**

Deep learning is a kind of ML that focuses on acquiring knowledge from data representations rather than relying on algorithms designed for particular tasks. Identifying the process by which deep learning achieves its results is often unattainable. Given the lack of a universally accepted meaning, we advise readers to minimize their usage of this phrase.<sup>viii</sup>

#### **Examples of ML in Chemistry**

Various applications have been thoroughly investigated and effectively used. Consequently, there has been a surge in the number of innovations and requests for patents in this domain.<sup>ix</sup>

One particular innovation, as outlined in 3M patent applications "WO2020/234718 and WO2020/170051, using a machine learning model to detect microbial contamination in food and water before conducting costly and time-consuming nucleic acid amplification assays to determine the quantity of target species. Applying ML in this manner may effectively decrease the expenses and duration required for identifying pathogens in food while safeguarding public health against the risk of foodborne bacterial illnesses.<sup>x</sup>

WO2020/243643, an application by Harvard College, describes an inventive use of ML in mass spectrometry. Using this technique, even trace amounts of regulatory molecules may be identified and detected, including signaling proteins and membrane receptors. This technology also enables the concurrent execution of high-throughput proteomics experiments, significantly enhancing the effectiveness of detecting and identifying complicated samples.ML has been used innovatively in the operating theatre within the MedTech business. WO2021/033061, known as 3M, outlines a continuous video-based product authentication method.<sup>xi</sup> This method enables the automated delivery of product-specific instructional content to medical professionals. Furthermore, the ML model may be trained to identify the alterations a product experiences when administered to a patient and evaluate adherence to optimal protocols.

# What Separates Software from MI, Fundamentally

The fundamental objectives of both software and ML are very comparable. Both are designed to address intricate human issues by gaining a deeper comprehension of the problem domain. Software facilitates task automation by specifying a set of instructions for a computer to follow.<sup>xii</sup> In contrast, ML enhances automation by autonomously generating the rules required for the activity. Software development relies on human ingenuity to identify a problem

and articulate a solution in the form of a detailed computer program. The input data and the projected output values are often collected simultaneously by ML data scientists.

The computer then attempts to locate an application that will give a result for each possible input value.<sup>xiii</sup> The principle is elucidated in the diagram shown in Figure 2 below:



Source: https://futurice.com/blog/differences-between-machine-learning-and-software-engineering

#### Figure 2: Difference between Software Program and ML

## Complexity of Proving Patentability in the Software Industry

A software patent is awarded for inventions that enhance computer performance through a novel computer application. Nevertheless, a software patent lacks a legally defined or precisely defined term. Furthermore, several nations worldwide impose distinct limitations on patenting software advancements. U.S. patent law prohibits the granting of patents for abstract notions.

This limitation is used to prohibit the granting of software patents.<sup>xiv</sup> The patentability of the subject matter is crucial for obtaining the software patent award. The following paragraphs go into the difficulties associated with establishing the patentability of an invention.

For instance, a software program might use intricate systems to outperform or equal a physical process or piece of equipment, making it difficult to categorize the software program as a novel innovation, method, or design. Furthermore, it should be noted that not all inventions and developments are bestowed with patent rights. For instance, scientific theories, mathematical methods, and processes are not eligible for patent protection.

Now that we have grasped the fundamental concepts of software patents and the challenges associated with demonstrating their patentability let us explore methods for obtaining a software program patent in India.

#### Patenting Software in India: The Steps to Take

When compared to other fields of technology, acquiring a patent for a software application in India is particularly tough. The claims of such a patent should highlight the traits that demonstrate technical effectiveness and advancement; thus the applicant should focus on them while writing the application.

In addition, the specification of the software patent application must include convincing evidence for these claims. The chance of securing patent approval would improve dramatically with the implementation of such an approach.

The primary criteria for software patentability include innovative steps, novelty, industrial applicability, and the ability to overcome Section 3(k), which deems algorithms and computer programs ineligible for patent protection. Applications must be submitted focusing on the key aspects outlined in Section 3(k). Having gained comprehension of the process of patenting a software product in India, let us now delve into the methods of formulating claims and specifications in software patents.<sup>xv</sup>

The five basic steps involved in creating claims and specifications for a software patent are as follows:

- Think of the new idea as a way to fix an existing issue.
- Create a clean and well-labeled flowchart covering all the aspects and capabilities of the invention that have been shown.
- Create a network diagram that shows how the main pieces of hardware are linked.
- The block diagrams and the flowcharts should be in sync with one another.
- Complete block diagrams and method claim components should be included in any draft patent claims for equipment or systems.

#### AI/ML Patents

The laws governing patents in the United States state that it is impossible to patent an ML algorithm directly. On the other hand, the legislation does make it possible to patent a sequence of steps that make up an algorithm. The reasoning for this is based on the fact that, according to United States patent law, an algorithm is considered a set of mathematical steps and operations. Therefore, although getting a patent for software is possible since it is deemed a completed product, it is impossible to patent ML algorithms because they are considered abstract.<sup>xvi</sup>

#### Key Concerns Regarding the Applicability of Ai/Ml Patents

Subject matter involving AI or ML may be eligible for patent protection if it satisfies two criteria: first, it must perform a technical function; second, it must provide a technological benefit beyond improving speed or efficiency. The use of AI and ML in a routine setting to solve a problem predictably does not fulfil the conditions for being eligible for a patent, therefore removing it from the privilege of being eligible for one. Applications for patents related to AI and ML are only considered eligible for patentability if the whole invention is regarded as having been enhanced by a technological contribution. A neural network, a kind of algorithm for ML, has been integrated with cardiac monitoring equipment to identify abnormal heart rhythms. This integration represents a step forward in the development of technology.

Now that we have a fundamental grasp of patents for AI and ML and the crucial variables to consider when establishing the eligibility of such innovations let us investigate creative techniques for creating claim specifications for software patents.

The acronym CII stands for computer-implemented innovation, and one of its subcategories is ML.

However, when evaluated against the criteria for patent eligibility, ML shows no unique characteristics. The EPO evaluates the innovative stages of CII innovations using the Comvik technique, which was developed by the EPO Boards of Appeal in case T 641/00.

The EPO uses what is called a "problem-and-solution" approach to evaluate the inventive step. This entails identifying and assessing the gaps between the innovation at hand and the nearest existing technological analogue. Next, patent examiners will determine a" objective problem," which is a made-up problem that has to be addressed using the most similar existing technology to the proposed solution.

The question that has to be answered concerns the degree to which the suggested solution to this difficulty is evident, given that it is supplied by innovation. The problem-and-solution technique used for computer-implemented ideas has undergone some minor adjustments at the hands of Comvik.

The EPO now demands that particular technical distinctions exist between the invention and any existing prior art to grant a patent. In addition, these technical distinctions need to provide a technical answer to a technical predicament. A computer-implemented invention has to make a discernible and practical improvement to the operation of a machine in the real world for it to have a chance of being granted a patent. This is necessary for the innovation to be considered novel.<sup>xvii</sup>

When determining whether or not a method of ML may be patented, the same factors should be considered. In the realm of ML, the most significant issue is whether or whether the approach delivers a technical solution to a technical issue based on the data that is most closely associated to it.

The use of this test is contingent upon the nature of the innovation since there are generally three categories of inventions that may utilize AI/ML:

#### AI invention type 1 - 'Core AI'

These advancements deal with standard ML techniques and have no intended use beyond that. These are computational mathematical techniques. The EPO would have substantial difficulties securing intellectual property rights for such technologies. Since it is a mathematical technique without any technical consequence, the EPO is unlikely to grant a patent for this development. Fortunately, these concepts are unlikely to be encountered by chemical patent attorneys.

#### AI invention type 2 - Generating a training set or training a model

An ML algorithm is often taught using a training set, a collection of fundamental data stored in a database. For instance, an ML system employing optical character recognition may use a training dataset of many characters that human users have previously categorized. A patent application might be derived from the training set itself or the methodology used to train the algorithm. Implementing these innovations may present challenges in terms of protection since establishing a direct correlation between a training set and a technical outcome is sometimes arduous.

The algorithm training process is conducted alone inside a computer without external involvement. Implementing the recommendations provided by the Enlarged Board of Appeal in G1/19 will pose difficulties in safeguarding innovations of this kind. According to the ruling in G1/19, no specific kind of innovation is automatically precluded from being eligible for patent protection. However, if a process is carried out only inside a computer, it will be challenging to demonstrate a technological outcome unless it somehow enhances the computer's functionality as a machine.

#### AI invention type 3 - AI as a tool

Inventions of this sort include the application of ML to a specific domain where its technical implications play a defining role. This is the most promising path to patent approval for hopeful inventors. As such, a technological outcome may be achieved by using ML methods to automatically regulate the focus of a microscope. In another example, an ML strategy that manages the relative concentration of chemicals in an industrial process is likely to offer a technological benefit.<sup>xviii</sup>In these contexts, patent lawyers are most likely to encounter ML. In these situations, the answer to the issue of whether the ML approach in question includes a technical solution to a technical issue will be deciding.

#### CONCLUSION

This study explores the diverse environment of AI and ML, including worldwide competitions, patenting methods, software difficulties, and the nuances of patentability. As we explore many aspects of this technological landscape, it becomes clear that AI is not only a scientific progress but also a crucial global need for governments.

An examination of patent data reveals the dynamic character of technological advancement, as seen by the worldwide competition in AI. In recent decades, there has been a significant increase in the number of nations focusing on AI technology. The spike, especially prominent in the 1990s, highlights the increasing acknowledgement of AI's potential and business significance. The emergence of the United States and China as prominent contenders in AI demonstrates their unique approaches to investigation and discovery. Japan and several European nations are seeing a decrease in importance, while the US and China are emerging as influential leaders, each approaching the field of AI in their distinct ways. The use of novel indices, namely the National Breeding Ground (NBG) and the International Breeding Ground (IBG), enhances the study by providing insights into market attractiveness and the extent of patent safeguarding across different countries. These indices comprehensively comprehend nations' endeavours to allure international innovators and protect their AI-related IP. The need for legal frameworks and international collaboration becomes more crucial in the unrelenting quest for AI supremacy. The international community must confront issues related to standardization, cooperation, and the intricate equilibrium between promoting innovation and safeguarding intellectual property. As we explore the methods for discovering AI patents, the effectiveness of a keyword-based strategy becomes evident. The value of keywords in capturing the substance of AI patents is underscored when compared to tactics based on IPC codes. The efficacy of this strategy in producing a dataset of superior quality highlights its significance in addressing the complexities arising from the varied categorizations and understandings of patent offices around the globe. The results underscore the significance of flexible and agile approaches in the alwayschanging realm of technological investigation.

The study explores the intricacies of patentability in the field of software patents in India. The lack of a precise legal definition for software patents and the varying limitations of different nations present significant issues. The discourse on obtaining a patent for a software program in India explores the essential components of creating applications, focusing on the technical impact and addressing the restrictions outlined in Section 3(k). The strategic methods presented provide a clear plan for successfully securing software patents in an Indian setting. ML is a crucial subfield of

AI that allows computers to learn without the need for explicit programming. Deep learning, a subcategory of ML, functions by acquiring knowledge about data representations instead of relying on algorithms designed for particular tasks. The patentability of ML in Europe is analyzed using the Comvik technique, highlighting the need for a technical solution to a technical issue.<sup>xix</sup>The classification of AI innovations into core AI, training set-related AI, and AI as a tool provides a valuable understanding of the patentability scenario, with the latter emerging as the most promising path to success.

The report finishes by emphasizing the interdependence of legislative frameworks, technical advancements, and global competitiveness in influencing the path of AI and ML. The exploration of several aspects, ranging from international competitions for patents to the intricacies of software and the issues of patentability in ML, uncovers the complicated interplay between innovation and regulation. In the face of an imminent technology-driven future, the harmonious interaction between legal frameworks and technical breakthroughs will have a crucial impact on shaping innovation, safeguarding intellectual property, and guiding worldwide progress. The investigation conducted in this study functions as a navigational tool, directing those involved in the unexplored domains of AI and ML, where the convergence of law, technology, and creativity drives humankind into novel territory.

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