Blockchain-Supported Patent Transparency Mechanisms in Pharmaceutical Innovation

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***Abstract*—Although there has been an increase in patent transparency globally within the pharmaceutical industry as a whole there still exist numerous issues within this area due to the fragmented nature of the patent databases, inconsistent manner of reporting patent status, and delay in updating the secondary patent information associated with each patent. These types of issues have contributed to many types of regulatory uncertainty, strategic patent extension practices, and information asymmetry among innovator companies, generic drug manufacturers, regulatory bodies, and the public. This research aims to examine the viability of developing a blockchain based patent transparency system for improving the integrity of patent lifecycle data, tracing patent lifecycle events, and synchronizing patent lifecycle event data. The study discusses the legal and regulatory implications of implementing a blockchain-based patent registry (TRIPS, National Patent Regimes) and how it can provide enhanced auditability of patent lifecycle data, and decreased information fragmentation; however, acknowledge that there are numerous technical, governance, and institutional barriers that need to be addressed before such a system can be implemented.**

Keywords— blockchain, pharmaceutical patents, patent transparency, distributed ledger technology, smart contracts, intellectual property governance.

I. Introduction

The pharmaceutical industry depends heavily upon patent law to recoup investment made in research and development as well as to protect those investments from unauthorized reproduction or production. Through the issuance of a patent, a firm is granted exclusive rights to a product, process or method of manufacture (or improvement thereto) that allows them to recapture their R&D expenditures associated with discovering the product; conducting the required clinical trials; obtaining regulatory approvals to sell the product; and meeting post-marketing requirements. Although this system is designed to encourage innovation in pharmaceutical products, there are growing concerns about the clarity and accessibility of patent information [1].

There exists an ongoing problem related to fragmented patent data. A pharmaceutical company typically files its patents in several countries, each of which has different laws governing patents, as well as different standards governing how patent documents are prepared and maintained. Therefore, patent information is scattered among national patent databases; regulatory filings; and court records. Because of the fragmented nature of patent data, determining all relevant patents for a particular drug is often complex and especially so if secondary patents exist (e.g., formulations, dosage forms, uses, etc.).

Additionally, secondary patents add to the complexity of transparency because they can extend the length of time market exclusivity extends beyond the life of the original compound patent. Furthermore, the cumulative effect of these patents creates uncertainty for generic manufacturers; regulatory authorities; health care providers; and payers, making it difficult to determine patent status for a drug. It also requires significant legal and technical effort to determine patent status; thus, increasing transaction costs and slowing down the introduction of generic versions of drugs into the market. A second issue related to transparency is the lack of timely and uniform public disclosure of patent information. Patent applications are not published until after a certain time; and the status of patents may not be changed immediately in publicly available systems. For example, a court decision; opposition; or revocation of a patent can affect the scope of protection; however, changes in patent status may not be consistently documented in all systems; therefore, creating informational asymmetry between originator firms and other players in the pharmaceutical marketplace [2].

Figure 1 illustrates a simplified conceptual model of the proposed blockchain-based patent transparency model. Official patent data continue to reside in national patent office databases where they will remain the sole source of comprehensive documentation.

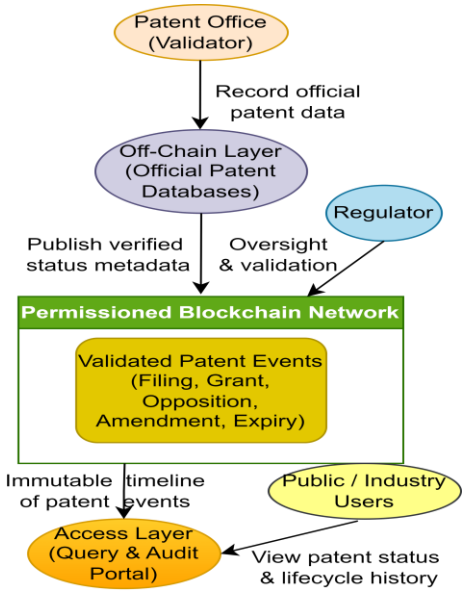

Fig.1. Conceptual framework for blockchain-supported pharmaceutical patent

A blockchain-based system for pharmaceutical patents provides a single, timestamped record of major patent

events. Major patent events may include: filing; publication; examination results; grant; opposition; license agreements; and expiration. In this way, by creating a single ledger that all authorized stakeholders can view at the same time, the system has the potential to reduce differences between databases and reduce reliance upon various fragmented sources. This research analyzes the feasibility and consequences of using blockchain as part of pharmaceutical patent transparency systems. The purpose of the research is to determine if a distributed ledger system can address some of the deficiencies currently inherent in the manner in which patent information is managed.

II. Review of Literature

While the growth of the body of literature on the application of artificial intelligence (AI) in primary education is increasing as well as the amount of research being conducted in this area, it appears that there is a lack of coherence within the literature as to what areas of focus or scope should be emphasized [3].

The literature on AI in elementary education describes multiple types of tools that may be used at the school level, such as intelligent tutoring systems, adaptive learning platforms, automated assessment applications and learning analytics dashboards. The overall intent of most of these tools is to aid teachers in their role, by completing routine tasks and by providing personalized learning opportunities for students. Most of the tools will contain features that allow for adjustment of instructional content based upon student performance, the tracking of student engagement through a variety of measures, and the delivery of real-time feedback to students. The purpose of these tools is to increase the responsiveness of the teaching process to the needs of individual students and to decrease the administrative load on teachers. While teachers are expected to utilize the data produced by these tools to identify the needs of their students and to modify their instructional strategies accordingly, a large body of evidence from both experimental and quasi-experimental implementations of these tools demonstrates that the effectiveness of implementing AI into elementary education is dependent on several factors, including sufficient infrastructure, teacher preparedness to use these tools, institutional alignment to support the use of these tools, and consistent access to professional development [4].

Teacher job satisfaction has been one of the most widely studied topics in the organizational, psychological, and educational literature. A number of variables have been identified as contributing to teacher job satisfaction, including the amount of work required of teachers, whether teachers understand their role clearly, the degree of autonomy teachers have in deciding how to teach, the degree to which teachers feel valued by others, teachers' relationships with their colleagues and administrators, the degree to which teachers perceive themselves as receiving support from their supervisor, and the degree to which teachers perceive themselves as competent professionals [4].

TABLE I. REVIEW OF RESEARCH

Author(s) and Year	Focus of Study	Key Findings
(Bonnet et al., 2022)	Overview of AI use in education	AI supports personalized learning and automation but requires alignment with teacher needs [5].
(Qizi et al., 2024)	Systematic review on AI in higher and school education	Identifies emerging AI tools; highlights lack of research on teacher-related outcomes [6].
(Adekola et al., 2024)	Factors influencing teacher job satisfaction	Autonomy, support, and workload are central to satisfaction—relevant for evaluating AI tools [7].
(Bali et al., 2022)	Datafication and algorithmic influence in education	AI reshapes teaching through data metrics; raises concerns about autonomy and control [8].
(M. B., 2025)	Teacher satisfaction in Finnish schools	Positive work environment and support improve satisfaction; supports AI as a potential aid [9].
(Mohammed, 2024)	Critical analysis of AI in schools	AI can alter professional roles; warns against reduced human judgment in instruction [10].
(Kumar et al., 2024)	AI implementation in Singaporean classrooms	Teachers reported workload relief but raised concerns about feedback accuracy [11].
(Krishnan et al., 2025)	ICT integration in schools and teacher readiness	Success depends on training, leadership, and digital competence—critical for AI adoption [12].
(Hossain et al., 2024)	Teacher agency and technology in classrooms	Involving teachers in decisions leads to more positive views on technology integration [13].
(Almeman, 2024)	Ethical concerns in AI use in education	Raises questions about fairness, transparency, and algorithmic bias—factors affecting trust [14].

III. Patent Systems in Pharmaceutical Innovation

The pharmaceutical industry has been affected by the changes made in the TRIPS agreement in terms of patent law. The TRIPS agreement sets up minimum standards for the protection of patents for all countries who are part of the WTO (World Trade Organization). Each country has its own statute that outlines how the TRIPS agreement will be implemented into their patent laws.

- Pharmaceutical inventions are eligible for protection in most countries for novel chemical compounds; formulations of known compounds; manufacturing processes for either chemicals or biologicals; and use of a known compound to treat a disease, when allowed. In order to be patented, the invention must meet three main criteria: novelty; inventive step; and industrial applicability. These three criteria are evaluated by the patent office in the country of origin. Pharmaceutical companies usually file multiple patents for one product. Usually, there is a primary patent filed for the active pharmaceutical ingredient (API) of the product. Other patents may be filed for crystalline forms of the API; combinations of the API with other drugs; delivery methods; or improved manufacturing methods.
- Patent Life Cycle: The life cycle of a patent in the pharmaceutical industry starts with filing of a patent application. The patent application includes a detailed description of the invention and defines the

scope of protection through claims. After a set amount of time, which varies per country, the application is usually published, and this occurs at least eighteen months after the filing date or priority date. After the patent application is published, the application undergoes substantive examination by the patent office. The patent examiner evaluates whether the claimed invention meets the required standards in the patent statute. This evaluation may include written objections from the patent examiner, amendments by the applicant, and/or an oral hearing. Depending on the jurisdiction, this process can take several years to complete, especially for those applications involving complex technologies. Once the application meets the required standards, the patent is granted, and the grantor receives the right to prevent others from making, selling, or importing the invention without permission in the jurisdiction [15].

- Evergreening and Secondary Patents: The practice commonly referred to as "evergreening" is the practice of applying for secondary patents that are related to an existing pharmaceutical product so that the secondary patents can be used to extend the exclusivity of the original product. Secondary patents may claim new formulations, dosage regimens, polymorphs, combinations, or specific therapeutic uses. While such patents may reflect legitimate technological advancements, there is concern that secondary patents do not represent significant therapeutic advancements, but rather serve to delay the availability of generic alternatives. The cumulative effect of multiple overlapping patents creates confusion and uncertainty about when the protection afforded by the patents expires for a particular drug. When a patent thicket forms around a product, there is no clear indication of when the protection afforded by the patents expires.

IV. Transparency Gaps in Current Patent Ecosystems

There is a need for access to complete, up-to-date patent data; however, there is a significant variation of this access among the different groups involved in pharmaceutical patenting. The largest and most well-funded pharmaceutical companies (originators) maintain comprehensive internal files of all aspects of their patent portfolio, including pending application details, claim amendments and litigation strategy. Smaller generic firms, and public institutions, however, must rely on publicly accessible patent databases that may contain partial or out-of-date information. This disparity results in an information gap - generic firms must make decisions based on incomplete information with regard to the validity and extent of relevant patents prior to entering a new market. Generic manufacturers will delay entry to the market if they are uncertain whether their actions would infringe on existing patents. At times, the lack of clarity in patent status can deter competition entirely. Healthcare institutions and procurement agencies are also impacted by the lack of clear patent status. Uncertainty about the current status of a patent can impact the ability of public health institutions to negotiate prices, and develop reimbursement policies. Without a clear understanding of patent status, public health decision making processes may be based on estimates rather than verifiable patent records.

- Fragmented Patent Data Sources: Patent information is stored in numerous jurisdictions around the world and within each jurisdiction there are differing types of patent databases. National and Regional Patent Databases store patent information in different manners, each with different classifications, search capabilities, and documentation requirements. International patent databases compile patent information but do not consistently reflect the current legal status of a patent. A single pharmaceutical product can have patents protecting it in multiple countries. To track these filings it is necessary to consult individual databases. Information regarding the legal status of a patent (e.g., grant, revocation, amendment, expiration) can be documented differently across systems. There is no standardization of terminology and procedural codes used in recording patent legal status, and this makes cross-country comparison difficult [16].
- Delays in Public Patent Disclosure: Most patent systems require publication of pending applications at a minimum of 18 months after the filing date. The pre-publication period is confidential to protect applicant's interests. However, during the pre-publication period, information regarding pending applications is not available to other stakeholders. Even after publication, it may take some time to update the public database with current patent legal status. It may be some time before the outcome of the examination process, amendments made to the patent application, oppositions filed against the patent application, and/or court decisions related to the patent are reflected in official patent records. Delays in updating patent legal status records in rapidly changing pharmaceutical markets may lead to confusion regarding the enforceability of rights. Post-grant changes to a patent can substantially limit the scope of a patent. For example, a patent may be partially invalidated or narrowed as a result of opposition proceedings or litigation. Failure to update public patent records to reflect post-grant developments in a timely manner may cause stakeholders to rely on outdated patent status information[17].
- Cross-Jurisdictional Patent Status Discrepancies: Pharmaceutical patents are territorial and therefore, the same invention can receive a patent in one country and be denied a patent or receive a limited patent in another. Different countries apply different standards for examining and enforcing patents. For example, different countries may have varying interpretations of novelty, inventive step, or what constitutes patentable subject matter. Additionally, judicial reasoning may differ across different legal systems. For example, a court in one jurisdiction may hold a patent invalid that is still valid in another jurisdiction. Disparate patent statuses across

countries complicate global assessments of patent protection. Additionally, not all countries provide the same level of procedural mechanisms to challenge patent grants (e.g. pre-grant opposition, post-grant review, patent term extension) [16].

V. Architecture of a Blockchain Supported Patent Transparency Framework

Governance rules must outline the process for admitting new participants into the network, validating updates to the data, and resolving potential disputes involving data entry. Each recorded transaction must refer to a legally-verifiable event, including filing of an application, publishing, granting, amending, opposing, transferring ownership, registering license agreements, rendering judicial decisions or expiring. Each transaction will also include metadata fields that indicate jurisdiction, patent number, date, and status changes. It will be important to establish standards for the data format used to ensure consistency across jurisdictions.

- Blockchain Model: Selection of the blockchain model is essential to defining the system architecture. A permissionless blockchain enables any participant to enter the network and verify transactions. While a permissionless model provides maximum openness and flexibility for all participants, it raises many issues regarding confidentiality, governance and regulatory compliance in the context of patents. A permissioned blockchain limits participation to pre-identified and authorized entities. Validator nodes may be run by patent offices or institutions appointed to run them. Access rights can be set up so that selected patent information can be publicly viewed while transaction validation is limited to approved parties. In light of the sensitivity of patent applications prior to publication and the necessity of regulatory supervision, a permissioned system is the most congruent model of administrative governance. Such a model facilitates managed access, identity verification and accountability mechanisms [18].
- On-chain vs. Off-chain Data Management: Patent documents contain large amounts of detail regarding technical descriptions, chemical structures, etc., in addition to confidential information. The hash of the official document stored on the blockchain serves as a verification mechanism. Should a document be modified, the hash stored on the blockchain would no longer match the hash of the referenced stored document.
- Integration with Existing Patent Office Systems: To operate successfully, a blockchain-based transparency framework will have to be able to interface with existing patent office systems. Patent office's already have well-established digital infrastructure for filing, examination and maintaining records of patents. Therefore, integration should occur through compatible interfaces as opposed to replacing existing systems. Interoperability will likely require application programming interfaces (API) to automatically transmit authenticated status updates from internal databases to the blockchain ledger. When a patent is granted, amended or canceled, the internal database will create a transaction request to update the blockchain ledger. Validation rules will authenticate the update before recording the transaction [18].

VI. Real Case Studies And Applications

- Blockchain in Pharmaceutical Supply Chain Traceability: Blockchain has been extensively researched for use in the pharmaceutical field particularly in relation to drug supply chain traceability. A consortium of pharmaceutical manufacturers and distributors created the MediLedger Network which was established to help ensure compliance with the U.S. Drug Supply Chain Security Act. The MediLedger Network utilizes a permissioned blockchain to verify product identifiers and provide record-keeping capabilities amongst authorized parties. Manufacturers, wholesalers and dispensers act as validated entities in this model. The primary goal is to identify counterfeit products and track all distribution [19].

Relevant lessons learned from the Medi Ledger project apply to patent transparency systems as well. First, a permissioned architecture fits better in the context of a regulated environment in which participating entities are known institutions. Second, the operational stability of a blockchain-based system relies heavily upon governance rules and legal agreements amongst consortium members.

- IBM's use of Blockchain Technology in Healthcare Data Integrity: IBM utilizes blockchain technology to collaborate with healthcare organizations to provide a secure means to exchange medical information and document clinical trials.

Projects in healthcare must conform to the appropriate data protection law and confidentiality agreements; therefore, access control methods that are structured and encryption must be utilized to prevent unauthorized release of information. Similarly, safeguards for unauthorized release of information must be established in the administration of patents [19].

- Estonia's National Blockchain Infrastructure: Estonia has employed a blockchain-based technology (Keyless Signature Infrastructure) in their public administration systems for protecting government records; while it is not exclusively focused on patent information, the system provides cryptographic verification for health, judicial and legislative records. In this manner, Estonia illustrates that blockchain inspired systems may be scaled to operate at a national administrative level. Cryptographic signatures are assigned to each data transaction providing a time stamp allowing for identification of unauthorized modifications. Estonia's model provides a method of increasing public trust in digital governance through the transparency afforded by the verification mechanisms, and for patent transparency initiatives, it shows how a distributed ledger

architecture may be integrated into official registries without reducing the institutional authority responsible for decision-making regarding the content of those registries [20].

The entry into the blockchain functions as a complementary verification mechanism.

Lessons learned: There were many similar lessons that were learned from all of the examples reviewed above. First, Permissioned Networks are most applicable for use in regulated industries, which can be thought of as Healthcare and Intellectual Property Administration. Second, Blockchain Platforms are more useful to the degree that they improve Data Integrity, rather than replace Institutional Databases. Third, the Practical Feasibility of Implementing a Blockchain Platform will depend on whether it can Interoperable with Digital Infrastructure that currently exists. Fourth, Legal Recognition of Entries in Distributed Ledgers are equally important components. Administrative and judicial bodies must recognize blockchain entries as reliable forms of evidence [21].

Additional lessons learned include the fact that blockchain functions best as a verification layer as opposed to a storage solution. The institution retains ownership of sensitive data and the blockchain provides proof of authenticity and sequencing. This model is similar to what is needed in patent transparency frameworks. Finally, both examples highlight the need for regulatory clarity and participation incentives. Without regulatory clarity and mutual benefits, participation in a blockchain network will likely be limited. Technical feasibility alone does not guarantee the sustained implementation of a blockchain platform [22].

VII. Benefits and Limitations

The use of a blockchain-supported patent transparency platform will provide greater clarity to stakeholders regarding the legal status of pharmaceutical patents. The ability to create and timestamp structured updates to the status of patents will help to alleviate some of the uncertainties created by the fragmentation of patent information across disparate databases and delays in reporting. Patent offices and other relevant authorities can rely upon a common record of official action. In addition, public access to non-proprietary patent status information can increase public confidence in the patent system, especially in those areas where the exclusive rights granted through patents directly impact medicine pricing and availability.

- Reduction of Pharmaceutical Patent Disputes: Many disputes involving pharmaceutical patents occur because of discrepancies over issues of priority, ownership, amendment history, and/or expiration date. A distributed ledger, which uses verifiable timestamps and sequentially recorded information, can significantly reduce the number of factual disputes concerning procedural history. For instance, the cryptographic evidence provided by the filing date can support a firm's claim of priority. Similarly, the ownership of patents and licenses can be recorded in a manner that reduces ambiguity. When documents are supported by a tamper-resistant audit trail, courts and regulatory agencies will find it much easier to determine the validity of documents [23].
- Cost Savings: There are several potential ways in which the use of a blockchain-based patent transparency platform could result in cost savings. The first advantage is that the synchronization of updates across all participating institutions could reduce the number of duplicate efforts made by eliminating the need to manually reconcile data. Second, automated recording of events via smart contracts may reduce the need for manual processing and thus reduce costs associated with labour. Finally, consistent and accurate patent status information may lead to reduced transaction costs associated with conducting freedom to operate analyses. Additionally, the ability to view a single source of accurate information regarding the status of patents across multiple jurisdictions may save time and money compared to having to review multiple sources of information [24].
- Technical and Governance Challenges: While a blockchain-based patent transparency platform offers many benefits, there are technical and governance challenges to be overcome before a solution can be implemented. Some of these technical challenges include: (i) scalability, (ii) latency, and (iii) security. If the volume of transactions to the system exceeds the capacity of the underlying technology, the system may slow down or even fail. Additionally, integrating a blockchain based system into the existing systems used by patent offices will add significant complexity [25].

VIII. Conclusion

Patent transparency for pharmaceutical products continues to be hampered by a lack of consistency across fragmented registries, different standards for filing reports, delays in updating patent statuses and poor coordination across countries regarding patent status and timelines. These structural shortcomings have led to an uncertain environment for determining the breadth of a patent; the number of secondary patent claims; the outcome of oppositions filed against patents; and the timing of when patents will expire.

This study analysed whether a blockchain-based registry system would provide solutions to these problems by using a structured governance and verifiable record-keeping methodology. The study developed a model for a permissioned distributed ledger (blockchain) architecture that provides validation and recording of all lifecycle events associated with a patent, such as filings, grants, oppositions, amendments, license entries, and expirations. The proposed architecture separates on-blockchain verification metadata from off-blockchain documentation while providing auditability and chronological integrity. Study also found that distributed ledger-based systems can enhance the ability to track changes, reduce asymmetric information, and increase the reliability of publicly available patent documents.

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