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PHARMA AND HEALTHCARE BLOCKCHAIN PLATFORMS

U.S. Patent No. 10,025,797 ("797")

SUPPLY CHAINS

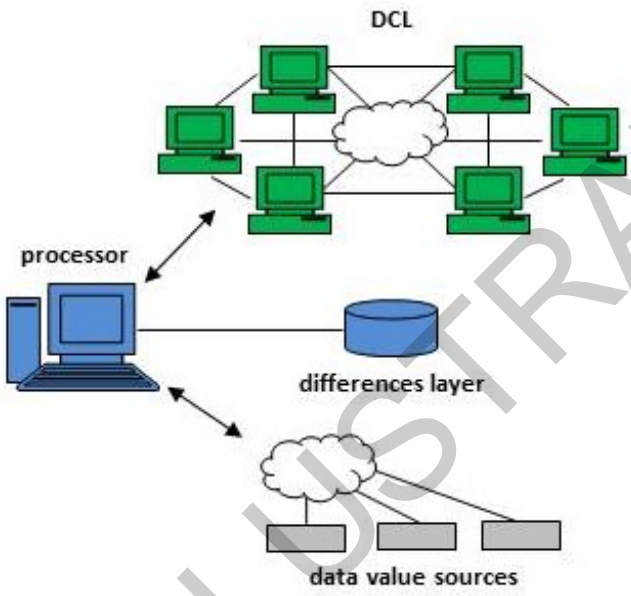
EXECUTIVE SUMMARY

The pharmaceutical and healthcare industries require the coordination of complex distribution channels, product authentications, patient safety, and increasingly detailed regulatory requirements. Pharmaceutical and healthcare networks have unique data security, privacy, and trade secret considerations which have limited the use of conventional network and ledger solutions.

As these industries respond to new challenges and recent global health events, the availability of fast, accurate, and standardized ledger systems is critical for participants and regulators.

As projects move out of their pilot phase, larger scale adoption will require a more integrated approach which includes real-time data linkages, cross-ledger techniques, and linked storage.

ILLUSTRATIVE APPLICATION



basic system components include:

(i) a distributed computer ledger (DCL),
(ii) a centralized or decentralized differences layer (DL),
(iii) data values (DV) and data value sources (DVS), and
(iv) a processor which executes inter-component operations

the figure illustrates a basic system where:

(1) manufacturing, customer, expiration, and channel data, values, and differentiating descriptors are inputs (DVS) to a differences layer (DL) operated by a processor,

(2) the processor creates records on a DCL, which are aligned with the DL, where the DCL "on-chain" records are an immutable set of records accessible to third parties,

(3) in some implementations, 3rd parties can selectively write to the DCL,

(4) the processor re-writes to the DCL relating to events including returns, recalls, advisories, and the safe-keeping of customer data, and

(5) third-parties can access & read the revisions to the DCL

'797 UNIQUE BENEFITS

'797's technology enables products and systems where transactions and transaction records are maintained on a blockchain or alternative distributed ledger, but where the processing and storage of descriptive and/or numerical values are maintained "off-chain". Traditional "smart contract" arrangements are built around "on chain" operations and "on-chain" external data calls which raise problematic storage, efficiency, and security concerns. '797 separates elements of processing and storage between "off-chain" and "on-chain" components for improved security, data integrity, and improved computer processing efficiency.

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COMPETITIVE SPACE

Pharmaceuticals and healthcare remain one of the great proving grounds for blockchain ledger technologies:

- COVID-19 collaboration is demonstrating real efficiencies for drug development and manufacturing
- increasing numbers of distribution and delivery channels make tracking and tracing more important
- increasingly complex regulatory requirements are best satisfied with scalable and univeral data solutions

DRUG SUPPLY CHAIN SECURITY ACT (DSCSA)

DSCSA project report lists their working group participants which includes manufacturers, healthcare providers, major retailers, and logistics companies. Listed participants include: Amgen, FedEx, Lilly, Pfizer, Sanofi, Walgreens, and Walmart.

The DSCSA is a directive from the U.S. Food & Drug Administration which will require distributors and logistics pro-viders to report information to the FDA including immediate notifications relating to illegitimate products. Elements of the DSCSA roll out in November 2020, and full compliance is required by the end of 2023.

CURRENT AND PROJECTED SIZE

The U.S. Pharmaceuticals industry represents 40 to 50% of the global marketplace, and 2018 U.S. spending was approximately $485 billion. The combined impact of regulatory changes and global health challenges will accelerate the adoption of integrated ledger technologies.