Blockchain, IP and the pharma industry—how distributed ledger technologies can help secure the pharma supply chain

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What is 'blockchain'?

Blockchain technology can be defined as an open ledger of information that is distributed and verified across a peer-to-peer network, rather than through one central server. In other words, it is a computerized public ledger that can apply to almost anything you may usually save to a spreadsheet or database. Each transaction or block is transmitted to all of the participants in the network and must be verified by each participant node solving a complex mathematical problem. Once a block is validated, it cannot be modified without changing it across the whole network. Distributed ledgers are inherently harder to attack because, instead of a single database, there are multiple shared copies of the same database. As no single person, institution or company hosts or controls the information, the storing of the information on the blockchain is perceived as (nearly) unhackable. Different types of data can be added to a blockchain, from transaction information to photos, videos and design documents and the technology is developing further with new types of distributed ledger technologies (DLTs), such as hashgraph software, which is meant to address the scalability issues of traditional DLT technology. While the traditional concept of blockchain is an open and anonymous network, there are also 'private' blockchains, mostly of interest to the financial and insurance industries, which pre-screen who is allowed to administer the ledger.

Blockchain and intellectual property protection

Despite various potential hurdles to large-scale legal application (eg questions concerning the governing laws and jurisdictions, data security, privacy concerns and technical scalability), in the context of pharmaceutical and other intellectual property (IP)-heavy industries,

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This article

- 'Blockchain' and other distributed ledger technologies (DLT) rose to fame as the technology underpinning cryptocurrencies, such as Bitcoin and Ethereum.
- Multiple industries are now exploring possible applications for DLT, which have found new applications in brand protection and enforcement, marketing and customer engagement, thanks to their ability to create a secure, time stamped and incorruptible chain of information. Indeed, hardly a day passes without news of a new blockchain product.
- While not all these ideas will be feasible, it is now widely expected to have a transformative effect on intellectual property-heavy industries, especially those faced with counterfeit goods and parallel imports, such as the luxury and consumer goods and pharmaceutical industries.

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blockchain and related distributed ledger technologies offer obvious possibilities for both IP protection/registration and evidence, either at the registry stage or in court. These include evidence of creatorship and provenance authentication, registering and clearing IP rights, controlling and tracking the distribution of (un-) registered IP, providing evidence of genuine and/or first use in trade (and/or commerce). Blockchain may also be used for authentication and provenance purposes, such as the detection and/or retrieval of counterfeit, stolen and parallel imported goods. Most notably, in the context of the pharmaceutical sector, it can also be used to comply with traceability requirements. Another buzzword often cited in connection with blockchain is the concept of smart contracts and similar distributed ledger products, which may be used to establish and enforce IP agreements, such as licences and exclusive distribution networks, as well as for the transmission of payments in real-time to IP owners. While the term 'smart contract' is yet to be uniformly defined, smart contracts can be broadly described as computerized transaction protocols that execute the terms of a contract automatically, without the need for third parties. Smart contracts may be used to implement a contract without human involvement once the underlying binding contractual terms have been coded.

Counterfeit pharmaceuticals

A recent study by PwC (PricewaterhouseCoopers) states that the counterfeit pharmaceuticals markets are a €188 billion (US$200 billion) annual business, the largest of all counterfeit goods (PwC, 'Fighting counterfeit pharmaceuticals' (2017), available at https://www.strategyand.pwc.com/media/file/Fighting-counterfeit-pharmaceuticals.pdf (accessed 9 May 2018)). Fake pharmaceuticals are highly dangerous and can risk the lives of the consumers either because they are lacking in active ingredients or because they contain harmful ingredients. The percentage of fake goods in circulation ranges from an estimated 1% in the most secure markets, to about 70 per cent in developing regions. The World Health Organization (WHO) estimates that 50 per cent of drugs sold online are counterfeits and digital channels allow criminals to elude security barriers designed for traditional drug distribution networks.

Fragmented supply chains

Fragmented supply chains, in which data do not flow automatically, have been identified as a contributing factor and such is the scale of the problem that legislators are now taking action to flush counterfeits out of the legitimate supply chain. In the European Union (EU), the EU Falsified Medicines Directive 2011/62/EU (FMD) will introduce an EU-wide system which aims to secure the supply chain between pharmaceutical manufacturers and patients against counterfeits. By February 2019, the manufacturers of all prescription and certain non-prescription medicines will need to add specific safety features to their packaging: in particular, (i) a unique identifier comprised of a two-dimensional matrix code and human-readable information, and (ii) anti-tampering features. The unique identifiers will be uploaded to a European Medicines Verification System (EMVS) and, when the medicines are shipped to their point of sale, will be transferred into national verification systems. These features will mean that legitimate medicines can be tracked at each point of the supply chain and, when the medicine is dispensed to a patient, a pharmacist will be able to scan the unique identifier to verify that the product is genuine. Similarly, in the USA, the Drug Supply Chain Security Act (DSCSA), enacted by the US Congress in 2013, requires manufacturers and repackagers to add a unique electronically readable product identifier to the packaging of certain prescription drugs. This unique identifier is then used to trace the product and who has handled it, through the various steps of the supply chain and allows verification of the product's authenticity. The DSCSA also introduced obligations to quarantine and investigate suspect drugs, and to notify the Federal Drug Administration (FDA) of any illegitimate products.

Authenticity and traceability in the supply chain

Blockchain lends itself very well to achieving the aims of these legislative schemes. Some manufacturers already use interactive tags which allow users to objectively verify the origin of the products. However, unlike blockchain, these more traditional and established technologies link to a single source of information, such as a website. Therefore, although they make life more difficult for counterfeiters, they are still prone to corruption and copying. Blockchain technology does not suffer from this drawback similar to QR codes (abbreviated from Quick Response Code, a machine-readable optical label to store data) and NFC (near-field communication) tag since counterfeiters should be unable to alter the information on the blockchain. One of blockchain's core characteristics is that it creates a trustworthy and transparent record by allowing multiple parties to a transaction to verify what will be entered onto a ledger in advance, without any single party

having the ability to later change any ledger entries independently. Such technology already exists, eg London-based Qadre's blockchain solution is currently being tested by several large pharmaceutical companies.

This ability to add blocks of data to the chain also creates opportunities for the pharmaceutical industry to record details about a product's progress through various stages, from sourcing the raw materials to manufacturing and supply chain. Crucial in the context of counterfeit pharmaceuticals is the control and monitoring of the authenticity of the active pharmaceutical ingredients during all stages of production: raw material sourcing, manufacturing of the active pharmaceutical ingredients and manufacturing of the final products. Using DLT, manufacturers of pharmaceutical goods will be able to record where goods are placed on the market—allowing them to distinguish grey goods in cases of parallel imports and identify where they left the supply chain, eg where a drug shipment has gone missing. In the same way, blockchain could be used to monitor and control leaks from selective distribution networks and thus assist in enforcing such agreements. A real life example of this is the BlockRX initiative, which has been created to address drug supply chain integrity by leveraging the distributed ledger to manage the drug development life cycle. If this type of technology is combined with simple smart contract functions and/or a closed blockchain application, then this could ensure the integrity of the pharma supply chain and meet the legal requirements imposed by the new legislation. Beyond the basic traceability applications, DLT could also assist in cold chain monitoring, ie ensuring that pharmaceuticals have been stored at the right temperature in their passage through the supply chain, therefore complying with the various WHO, EU GDP, FDA and other guidelines and regulations.

Anti-counterfeiting and enforcement

Aside from compliance, DLT also has great potential for revolutionizing the pharmaceutical companies' own anti-counterfeiting and enforcement efforts. The traceability features described above are likely to enhance the effectiveness of customs programmes to prevent global trade in counterfeits. If a brand owner is able to tell customs about the security features that its genuine products should have, then the absence of such features is an easy way for customs to check whether a product is counterfeit. In the future, customs authorities may be able to benefit from using the same scanning technology as envisaged under the FMD and DSCSA. The presence of these features interacting with the blockchain also offers greater potential to engage and educate customers about the risks of counterfeits and provide the ability to verify whether the products they have purchased are genuine. This is becoming more important with increasing numbers of patients purchasing drugs online.

In conclusion, the various legal and technical requirements of the pharmaceutical industry could make it into one of the premier use cases for DLT outside fintech.