Countering the Counterfeits: The Role of Blockchain

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ABSTRACT

The business of counterfeits is often termed as a 'crime of the 21st century'; causing an economic and security threat not only for the manufacturers but also to the nation's welfare due to loss of tax revenue. Counterfeit drugs are dangerous and harmful, with its implications being more severe more than that of monetary value. As per the WHO's definition, the drugs that are classified as sub-standard, unregulated/unlicensed or falsified drugs and IP related infringed drugs are termed as 'counterfeits'. Most counterfeit drugs are 'trademark counterfeit goods', where some of them are useless and others are harmful. A recent Interpol coordinated operation named 'PANGEA VIII' has targeted illegal online medicine, rogue domain name registrars, electronic payment systems and logistical services. Most developing countries are currently facing the consequences of these type of counterfeits.

This decade has seen the emergence of a new disruptive technology known as 'Blockchain Technology' which is majorly used in financial transactions. Blockchain acts as a trusted agent by removing intermediaries, facilitating faster transactions and improving transparency.

This thesis analyzes the possibility of elimination of counterfeits by using the Blockchain technology. The aim of the thesis is to define the counterfeits, discuss the existing technologies to counter the counterfeits, and characteristics of the blockchain technology applied for the supply chain so that counterfeits are countered. But blockchain technology alone is not a panacea and cannot eliminate the counterfeits. With a combination of this technology, a robust legal system, a tamper-proof packing system and consumer awareness, it will lead to efficient and holistic approach to reduce the counterfeits.

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INTRODUCTION

Counterfeiting is regarded as the 'crime of the 21st century'[1] and according to the International Anticounterfeiting Coalition (IACC) 2012 report, it is the fastest growing crime business with a value of $600 billion per annum. Pharmaceutical crimes have been a critical issue worldwide, threatening public health especially in developing countries. Pharmaceutical crimes involve production and distribution of stolen, illicit or fake medicines. These crimes are detrimental to the manufacturers as Pharmaceutical Research and Development is a complex process which takes a number of years from drug discovery to its distribution. The lifecycle of drugs, from discovery to post market, includes basic research, non-clinical trials, clinical trials, licensing, manufacturing and distributing.[2] At each stage of the lifecycle the product should follow standard operating procedures and once the product is developed, the challenge of the manufacturer will be delivery of the genuine product to the intended customer. But the present pharmaceutical Supply Chain Management (SCM) is outdated and cannot withstand the latest cyber security threats. Weak SCM systems pave the way for counterfeits to enter into the distribution network which not only risks public health, but also shatters the public trust in genuine medicines.

To create the trust and eliminate the risk of counterfeiting drugs, blockchain Technology with strong characteristics of trust and transparency can be used. But how did this technology emerge? As is known, most western societies are built on the concept of '*trust'*, normally defined as a positive expectation that each party will act in honest and benevolent ways, without any fear of exploitation. But in the year 2008, the subprime crisis jolted not only the societies economically, but also people's faith in the banks, regulatory authorities and ultimately government.

Out of the crisis and trust deficit emerged the bitcoin technology (based on blockchain) which was pioneered by Satoshi Nakamoto in his paper "Bitcoin: A Peer-to-Peer Electronic Cash System". In the case of bitcoin, money is transacted between different parties without the fear of trust and mostly important intermediators like banks are eliminated. Once the third parties are removed the transaction costs are reduced, and there is faster facilitation of transactions and increase of transparency. The technology behind bitcoin, Blockchain, is rapidly expanding

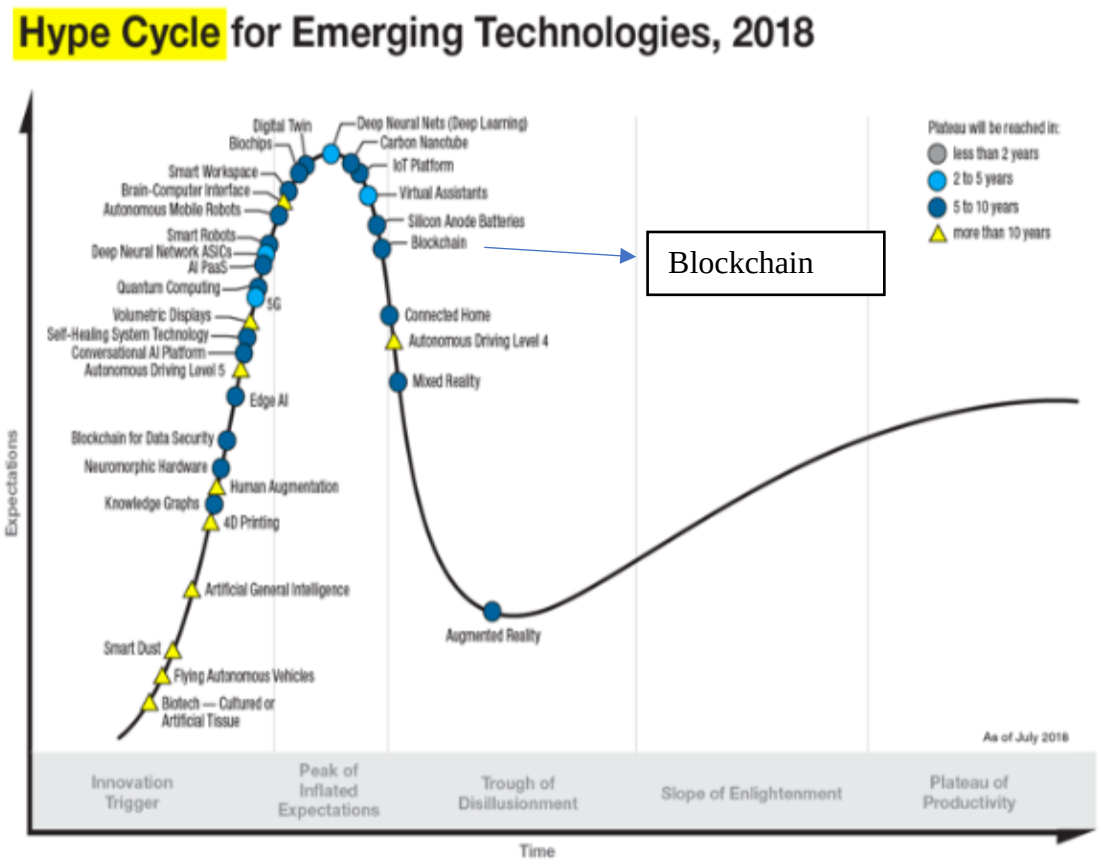
[1] Interpol Report, *'2000-2010 Interpol Fighting 21st century crime'* 2.
[2] Taiwan Food and Drug Administration, '*Taiwan Food and Drug Administration 2016 Annual Report'* 31. https://www.fda.gov.tw/upload/ebook/AnnuaReport/2016/E/index.html#p=1

from financial sector to other markets and the same principles can be applied to protect the genuine drugs.

1. **Gartner Hype Cycle**

The purpose of the Cycle is to interpret technology hype through the graphical representation of the growth, technology acceptance and how the use cases are solving the real industrial problems. As per the cycle, Blockchain is placed at the 'peak of inflated expectations' which means the technology is still in the infant stage.

However, within 5 to 10 years the Blockchain technology will reach the 'Plateau of Productivity' stage which means it will be widely used by the companies and some of them have already started on the experimental basis rather than as a enterprise.



Source: Gartner (August 2018)

2. Counterfeits classified

As confusion prevailed regarding the definition of the counterfeits, high level discussions have taken place at the WHO. Before 2017, the WHO defined counterfeit as "products deliberately and fraudulently produced and/or mislabelled with respect to identity and/or source to make it appear to be a genuine product".[3] As there was no clarity in this definition and to permanently eliminate the confusion WHO established a working group on refining the working definitions of Substandard/Spurious/Falsely Labelled/Falsified/ Counterfeit (SSFFC) medical products and devices.[4] The working group has produced the definitions for the *'Substandard and Falsified medical products'* and those were adopted by the Seventeenth World Health Assembly on 29 May 2017.

The working Group classified medical products separating substandard medical products from those that are deliberately/fraudulently making a misrepresentation (spurious, falsely-labelled, falsified or counterfeit) and those that are unregistered/unlicensed in the country of marketing.[5] The substandard medical products are those authorized products which fail to meet the quality standards and/or specifications, whereas unregistered/unlicensed are those which did not receive any permission or license from the national or regional regulatory authorities.

When it comes to falsified medical products, they are classified as deliberately/fraudulently misrepresented products related to their identity, composition or source. But falsified drugs do not fall under intellectual property rights. Falsified drugs are deliberate/fraudulent misrepresentation to any substitution, adulteration, reproduction of an authorized medical product related to labelling or packaging or documents, any ingredient or component and identification, including name and address of manufacturer, importer, exporter, etc.

Hence anything other than the above criteria can be termed as 'counterfeit' and is associated with the intellectual property rights. As per the TRIPS definition, *trademark counterfeit goods* are those goods, which uses identical trademark unauthorised or use of confusingly similar

[3] LaKeisha W, Ellen M '*The real impact of counterfeit medications'* US Pharmacist 2014, *39*, 44–46. https://www.uspharmacist.com/article/counterfeit-meds

[4] WHO report *Working Group of Member States on Substandard/Spurious/Falsely-Labelled/Falsified/ Counterfeit Medical Products*, 4th mtg, Agenda item 8, WHO DOC A/SSFFC/WG/5 (19-20 November 2015) Para 3.

[5] Seventieth World Health Assembly on *Member State mechanism on substandard/spurious/falsely-labelled/falsified/ counterfeit medical products*, Provisional agenda item 13.6, DOC A70/23 (20 March 2017) Appendix 3.

trademark which cannot be distinguished from that of a registered trademark can be termed as counterfeits.

Related to medical products, the term "falsified" adequately includes all types of deliberate misrepresentation of a medical products exclusion of intellectual property rights.[6]

3. Counterfeits: Key Players, factors and harmful effects

Did the classification help identify the counterfeits by the authorities? Who are key players involved in counterfeiting and what are the factors for the rise of such crime business? And what are the harmful effects of fake drugs?

The classification certainly improved international collaboration and investigation of counterfeits and sets standards for the enforcement agencies. Many nations had identified major players in the drug mafia who include manufacturers, importers, exporters, criminals and terrorist organizations, informal drug sellers and consumers.[7]

The factors that encourage counterfeiting are globalization and lowering of trade barriers, low investment and high profits, parallel trade, online prescriptions, inelastic demand, fragmented supply chain and weak national and international enforcement.[8]

Mostly developing countries are affected by the counterfeits and the factors contribution to the growth are lack of government will, inefficient regulatory authorities, high demand and less supply and unaffordable prices of genuine drugs.[9]

Some of the harmful effects of the counterfeit medicines:

IMPACT OF COUNTERFEIT MEDICINES	**CAUSES FOR IMPACT**
Increased Mortality and Morbidity	Due to adulterated and/or substituted ingredients for the API
Drug resistance	Due to subtherapeutic amounts of API in the drug product

[6] Id.
[7] Europol-EUIPO Situation Report, '*ON COUNTERFEITING AND PIRACY IN THE EUROPEAN UNION*' 2017, 32 – 42.
[8] Id.
[9] Foster S, '*Supply and use of essential drugs in Sub-saharan Africa: some issues and possible solutions'* Social Science Media 1991, 32 (1201–1281).

Reduced confidence in the health system	Due to the consequences of these counterfeit medicines, patients are skeptical of the western based modern medicines
Economic consequences	For patients and their families, providers of genuine medicines and overall country's economy is affected.
Adverse effects	Due to incorrect ingredients, where the effects may vary from being unexpected (e.g., when cotrimoxazole contains diazepam) to causing allergic reactions (e.g., artesunate tablets containing chloramphenicol).

Retrieved from Newton et al[10] and Wertheimer and Norris[11]

4. Legal obligations for drug supply chain: US, EU and China

The Falsified Medicine Directive (FMD) legislation which was introduced by the EU, introduced a new legislation for all the EU members to control counterfeits and also establish an efficient product recall system.[12] The EU legislation recommended two solutions; one, related to the physical product with an anti-tampering device, and the other a two dimensional barcode, carrying a unique identifier to store the relevant information at central data repositories. The manufacturers will upload the information contained in the unique identifier for each individual medicine at the production stage and the information is to be sent to **cloud based centralized EU data repository**. At the point of dispensation, the medicine will be scanned, checked and verified for authenticity against a national (or supranational) repository.[13]

[10] Newton PN, Green MD, Fernandez M, '*Impact of poor-quality medicines in the developing world'* Trends Pharmacol Science 2010, 31(99–101).
[11] Wertheimer AI, Norris J, *'Safeguarding against sub-standard/counterfeit drugs: mitigating a macroeconomic pandemic'* Res Social Adm Pharm, *2009*, 5(4–16).
[12] European Commission, Commission Delegated Regulation (EU) 2016/161(2 October 2015), supplementing Directive 2001/83/EC, (9 February 2016). https://ec.europa.eu/health/human-use/falsified_medicines_en

However the products which fall under the 'high risk falsification' are to be scanned at every stage of supply chain.[14]

The major disadvantage of the above system is that only authorized agencies can access the data, whereas access by patients/consumers is denied. Hence the end-consumer cannot check the validity of the product, he/she has to blindly believe the point of sale.

Similar to the EU Directive, the US Food and Drug Administration (FDA) passed the US Drug Supply Chain Security Act (DSCSA), the main goal of which is to build an electronic, interoperable system to identify and trace the prescription drugs.[13] The electronic system must be able to track, verify, detect and notify the FDA in the case of counterfeit products. This US system is little different from the EU, in this case the goal is to have complete transaction information so that data at each stage is collected.[14]

The trends in China are different than those in the EU and USA. In 2017, China launched a new '*two-invoice system'* wherein only two invoices can be raised along the supply chain i.e. from drugs manufacturer to wholesaler and finally to hospital/consumer.[15] The goal of this system is to encourage the manufacturer to become a distributer as well to counter the counterfeits entering into the supply chain.

The above three policies provide a great opportunity for the Blockchain to streamline the procedures and process of the supply chain management. However, before introducing Blockchain, it is necessary to analyze the existing technologies.

5. Existing Authentication Technologies

Organized criminals have become sophisticated and the need of the hour is to build novel technologies to detect counterfeits. Based on the literature available the technologies can be divided into the following:[16]

- Overt, or visible features
- Covert, or hidden markers
- Forensic/chemical techniques

[13] *Drug Supply Chain Security Act (DSCSA) 2016,* (US).
[14] *Id.*
[15] IYIOU Cooperation, *'Two Invoices System Is Imperative, the Opportunity to Reconstruct the Model of Medical Supply Chain Is Coming'* 2017. http://www.iyiou.com/p/37489
[16] Seventieth World Health Assembly on *Member State mechanism on substandard/spurious/falsely-labelled/falsified/ counterfeit medical products,* Provisional agenda item 13.6, DOC A70/23 (20 March 2017) 17.

- Track and trace models and technologies

5.1.Overt, or (Visible) Technologies

These technologies are normally visible to the naked eye and enables the consumers to easily identify the authenticity of the medical product. These technologies should be used in an environment of utmost security to avoid the mishandling by criminal organizations.[17] Further, it is to be carefully handled such that they cannot be reused or removed without causing any damage to the packaging or to the product, so that genuine products can be safeguarded from counterfeiting.[18] Any genuine overt product should include with tamper evident features for more security.

Some of the tamper-evident measures include:

i. **Tamper- evident micro cut labels** which are made of polypropylene. These labels consist of the small micro cuts placed on the closure flap of the packaging with added text "DO NOT USE IF SAFETY SEAL IS ALTERED OR DAMAGED". Before use, patients and health care professionals should check the security seal properly.

ii. **Tamper-evident VOID labels** are those once peeled off will leave an impression on the surface of the package as 'VOID' giving the evidence that the seal is opened or tampered.

iii. **Multi-destructible ("eggshell") vinyl labels** are self-destructible materials if trying to peel off.

iv. **Holograms**: In this, an interference pattern is formed between two-or-three dimensional mediums when a point source of light (the reference beam) of fixed wavelength encounters light of the same fixed wavelength arriving from an object (the object beam).[19] The diffraction pattern recreates the wave fronts of light from the original object only when the hologram is illuminated by the reference beam and by this reason original object is viewed as an indistinguishable image.[20] The hologram can be used as a security feature into tear bands in overwrap films, or as threads embedded into paper substrates and constitute a powerful two edged sword against falsification. However, hologram labels are easily and expertly copied and stimulated unless they are

[17] Buckley G, Gostin L, *'Countering the Problem of Falsified and Substandard Drugs, Institute of Medicine of the National Academies'*, National Academies Press, Washington, D.C, 2016, 155-273.
[18] *Id.*
[19] Tung H. Jeong, '*Basic Principles and Applications of Holograph'* 384. https://spie.org/Documents/Publications/00%20STEP%20Module%2010.pdf
[20] *Id.*

combined with other overt and covert technologies like scrambled images, micro text, UV-sensitive or other specialized inks.

v. **Optically variable devices**: these include the devices mostly image flips or transitions, often including colour transformations or monochromatic contrasts.[21]

vi. **Colour shifting security inks and films:**

These technologies show a variety of changes in colour when the product is viewed in different angles and are known as 'smart colours'.[22] It can be an effective security feature as an overt pack graphic element. And the colour shifting films include multi-layer deposition of thin films with unique diffractive properties, and vibrant colour transitions which can be used as tamper evident security seal.

vii. **Scratch-off technologies**:

When a layer of removable ink is scratched with a coin a code is found to prove the authenticity. The code is randomised to avoid criminals.[23]

5.2.Covert (Hidden) technologies:

The main purpose of the covert technologies in the supply chain is to enable regulatory authorities and stake holders in the chain to identify the counterfeit products. Patients will not have any knowledge about these features and they will be complex in nature so that criminals will find difficult to decode it. Some of them include:

5.3. Invisible Printing:

These are special markings which will appear only under certain conditions and they cannot be viewed with a naked eye.

For example, luminescent ink is not visible in normal light and it is classified as fluorescing and phosphorescing inks. Fluorescing ink is visible when exposed to ultraviolet light of specified wavelength.[24] Phosphorescent inks will continuously emit light for shorter period of time which can be detected with a reading device.[25]

The other inks like 'reactive ink' change its colour when subjected to ultra violet light, and infrared fluorescing pigments reacts only to specific wavelengths of invisible light. "Rub and

[21] Supra 19
[22] Marjan Kooroshnia, 'How to visually represent the colour theory of thermochromic inks' 2. http://www.diva-portal.org/smash/get/diva2:894513/FULLTEXT01.pdf
[23] Supra 19
[24] Julien Andres, Roger D Hersch, Jacques-Edouard Moser, Anne-Sophie Chauvin, '*A New Anti-Counterfeiting Feature Relying on Invisible Luminescent Full Colour Images Printed with Lanthanide- Based Inks'* 1.
[25] Id.

reveal", "coin reactive" inks are visible after rubbing with a coin.[26] Photochromic inks change colour based on wavelength of light whereas Thermosensitive or thermochromic inks, change colour at differential temperatures.[27]

Invisible printing image techniques includes different images consists of 'latent image' composed of letters, logos and figures, 'embedded image' is an image embedded into graphics which can be viewed only with special filter. Digital watermarks, hidden marks, micro text, anti-scan, safety fibrils, laser coding, odour etc. are some of the commonly used images to protect the genuine products.

A new invisible printing technique is being emerged known as invisible photonic technique mostly useful for steganography and watermarking for anti-counterfeiting purposes.[28] With this novel photonic printing technique, a variety of graphics with brilliant colours can be perfectly hidden in a soft and waterproof photonic-paper.[29]

5.4. Forensic/Chemical Markers

Most of these markers require laboratory testing or dedicated field test kits to provide the scientific proof of authenticity. Though there exist various technologies like chemical and biological taggants, isotope ratios, the most important is DNA-Nano taggants.

DNA taggants are distinctive combinations of synthesized DNA that can be applied to surfaces, objects, materials or personnel. Like nanometre-sized barcodes, they enable the origin of the tagged article to be verified, traced and monitored for movement.[30] These detection methods can provide rapid, reliable detection of DNA taggants in the field.[31] DNA taggants are an information assurance technology for objects with restricted access that verifies access and gives effective, covert tamper detection.[32]

5.5.Track and Trace Technologies:

This category of technology includes Radio Frequency Identification (RFID) tags and Quick Response (QR) codes. The tag or barcode is attached to the product and all the stakeholders in

[26] Supra 19
[27] Supra 19
[28] Haibo Hu, Jian Tang, Hao Zhong, Zheng Xi, Changle Chen, Qianwang Chen, '*invisible photonic printing: computer designing graphics, UV printing and shown by magnetic field' Scientific Reports* volume 3, Article number: 1484 (2013), 19 March 2013, 1.
[29] Id.
[30] John Reif, '*DNA Nano-Taggants for Covert Watermarking, Tracking and Communication'* AFRL-NNI science and technology achievements, 2009. https://www.nano.gov/sites/default/files/dna-nanotaggantsforcovert-afrl.pdf
[31] Id.
[32] Reif, *supra* 35

the supply chain can check the authenticity of the product. This system not only tackles the counterfeit problem but also gives the glimpse of the history of transactions across the whole product life cycle.

WEAKNESSES IN THE EXISTING TECHNOLOGY

Though existing technologies played a vital role in containing counterfeits with advantages such as overt features where patients and healthcare professionals could easily verify and check the product, the flip-side is that consumers are often not aware of the verification features. Further, those features can be reused, refilled, easily copied and sometimes provides a false sense of security. Similarly, covert technologies increase security measures by adding hidden messages but at the same time add supply complexity and cost. Forensic markers are too costly. And when comes to track and trace technologies RFID can easy be hacked[33] and QR codes can be replaced without any hard work.

In this hour, Blockchain strengthens and compliments the existing technologies. But the question that arises is whether Blockchain can act as a panacea to counterfeit problems? Can the idea behind the blockchain be successful in eliminating the counterfeits?

The Purpose of Blockchain

Blockchain technology today is termed as one of the major disruptive technologies and some even argue that it is a new form of B-internet which is ready to rapidly enhance the Web 3.0. The global systems are betting on blockchain to revamp their business models especially in the area of intellectual property rights. Francis Gurry, WIPO, Director General has recognized the importance of this technology and hinted about the "De-formalization" of IP and "private sector to be an ancillary record keeper".[34]

According to Don Tapscott and Alex Tapscott, the blockchain revolution is enabling 'Radical Transparency', embedding the principles of decentralization and sharing, threatening the archaic practices of the financial monopolies supported by politicians and bureaucrats which

[33] Stawomir Jasek, *'A 2018 practical guide to hacking NFC/RFID'* 2018. https://smartlockpicking.com/slides/Confidence_A_2018_Practical_Guide_To_Hacking_RFID_NFC.pdf

[34] Francis Gurry at, *'The Global Debate on Intellectual Property, Trade and Development: Past, Present and Future Conference'* 2017.

have enslaved the world in unescapable gridlock and removes the fat intermediaries who are reaping the benefits of the creators.[35]

Similarly, the blockchain revolution is taking place in the supply chain of the pharma drugs to counter the 21st century cyber-security threats. Blockchain tracks the events that happen along the supply chain and investigates the illegal activities along the chain. Buyers and sellers can easily validate the genuine product in the distributed ledger. Some of the features of the blockchain based SCM system for the drugs are:

- **Distributed Ledger increases Trust, Traceability and Transparency** – once the data is distributed in all the nodes of the stakeholders, they are able to track the pharmaceutical products throughout the supply chain without any trust issues. Anyone in the chain can verify the legitimate manufacturer, the authenticity of the product, and also safe delivery at each stage. Whenever there is a change in ownership of the drugs such changes are noted on the blockchain. Drug manufacturers and end- users can track their product at any time.
- **Visibility and Anonymity**: Both are opposite to each other similar to light and darkness where both cannot co-exist. However, in blockchain technology, it is possible to provide access to the original public date, while keeping private data confidential. For example, the condition and symptoms of the patient are made public, while the identity is kept private. Similarly, in supply chain the product details are made visible whereas the manufacturers secret techniques are protected.
- **Cryptographic Immutable block and Extended security:**
  Blockchain system is implanted with two kinds of cryptographic technology: one is Hash function and other is public/private key cryptography. Hash function is to link each block in the chain and public/private cryptography is used for identifying transactors and controlling access to data.[36] And for the data to get into the Block various Blockchain platforms resort to different consensus algorithms. For example, Bitcoin uses proof of work algorithms whereas Permissioned ledgers use a consortium of collectively trusted nodes to agree on the output of a consensus process, which are generally cheaper and faster than Bitcoin's proof of work.[37] And this thesis is based upon the consensus of permissioned

[35] Don Tapscott, Alex Tapscott, *'Blockchain Revolution: How the technology behind bitcoin is changing Money, Business and the World'* 2016.
[36] Blockchain White Paper, '*White Paper on the technical applications of Blockchain to United Nations Centre for Trade Facilitation and Electronic Business (UN/CEFACT) deliverables*' UN/CEFACT – Blockchain Project – P1049**,** 30 April 2018.
[37] Id.

ledger. Once after the validity the blocks are done each block is connected with a hash value of previous block into the new block. To tamper the one single block in the middle means to change the hash value of all previous Blocks which is impossible hence immutable.[38]

- **Data Analytics:**

  The supply chain produces huge data and it should be analyzed for further streaming of the technology and improving the efficiency of the drugs. For example, the effect and performance of the drug on the patients is recorded on the Blockchain where manufacturers can simply access the data for further research.

- **Smart Contracts:**

  A code that facilitates agreement between parties which is deployed on the Blockchain and is executed automatically as a part of the transaction is known as smart contract.[39] The advantage of this contract is involvement of the intermediators are removed and transparency is increased.[40] It also provides better security and lowering of transaction costs and removes risks involved with the traditional costs.[41] For instance medical insurance of the patient is automatically executed once the patient receives the treatment.

Related Work

The inception of blockchain technology took place early in this decade, becoming popular after the rise of cryptocurrency and other financial services. It became more popular after the launch of smart contract and blockchain technologies ventured into different fields. And recently the trend has started for the application of blockchain features for the supply chain management. Prominent technology company IBM has joined hands with largest shipping firm Maersk to create a Blockchain trade platform. And the platform known as 'TradeLens' has attracted 94 clients which include shipping liners, customs authorities and other public and private organizations.[42]

TradeLens removed the middleman and resulted in capturing of 160 million shipping events like origin of goods, cargo arrival times and documents related to commercial invoices,

[38] *Supra* at 42.
[39] Soundarya, Priyanka Pandey, Dhanalakshmi R,'*A Counterfeit Solution for Pharma Supply Chain'* EAI Endorsed Transactions on Cloud Systems, 11 April 2018, 2.
[40] *Id.*
[41] *Supra* at 45.
[42] *'IBM, Maersk launch Blockchain-based shipping platform with 94 early adopters'* 20 August 2018. https://www.computerworld.com.au/article/645426/ibm-maersk-launch-blockchain-based-shipping-platform-94-early-adopters/

shipping bills and bills of lading in near real time on the Blockchain network.[43] Novartis has established a separate Blockchain unit and the purpose of the unit is to identify counterfeit medicines and track temperature with real-time visibility for the stakeholders in the network.[44] Novartis IMI(Innovative Medicine Initiative) Blockchain Enabled Healthcare program aims to partner the pharma industry with a consortia made up of SME blockchain companies, universities, clinical labs, hospitals, patient representatives and others.[45]

And modum.io is the system which tracks the temperature of the parcels on the blockchain system and this same technology is being expanded to counterfeit products.[46] Another new project known as Chainsafe[47] is initiated to provide an open and integrated platform for monitoring vaccines. In this process vaccine vial is tagged with either a signed QR code or a NFC tag and it is scanned unto the Blockchain and distributed across the nodes. And the authenticity of the vial can be checked at every stage. Similarly, a novel Ethereum based application is built to avoid the supply of the counterfeits by using the technology of cloning of the RFID and finding out the real owners.[48]

And some of the other major companies which involved in similar services of reducing counterfeits include Blockverify, Chronicled, Everledger, Provenance, Skuchain, Verisart, Vechain, as most of them deal with luxury items, diamonds, electronics and pharmaceuticals.[49]

Blockchain Counterfeit Related Patents

A search has been conducted by using certain keywords on the WIPO patent search to find out the potential of the Blockchain technology. Leading countries in this technology were picked up for the analyses.

KEYWORDS	APPLICATIONS			
	PCT	USA	Australia	China
Blockchain	822	1242	152	173
Distributed ledger	1827	5253	485	20

[43] *Id.*
[44] '*Novartis explores Blockchain's potential for pharmaceuticals'*. https://www.ledgerinsights.com/novartis-pharma-blockchain/
[45] *Id.*
[46] Sacha Uhlmann, *'Reducing Counterfeit Products with Blockchains'* University of Zurich, 15 January 2017.
[47] See: https://chainsafetyinvestigators.files.wordpress.com/2016/09/chainsafe-concept-note-oct-20161.pdf
[48] Kentaroh Toyoda, Takis Mathiopoulos, Iwao Sasase, Tomoaki Ohtsuki, *'A Novel Blockchain-Based Product Ownership Management System (POMS) for Anti-Counterfeits in The Post Supply Chain'.*
[49] Uhlmann, *Supra 52 12.*

Blockchain and SMART Contract	336	465	52	13
Blockchain and counterfeiting	44	80	9	1
Blockchain and supply chain	283	394	39	2
Blockchain and Data Security	672	1056	104	11

Source: WIPO patent search as on 23.12.2018

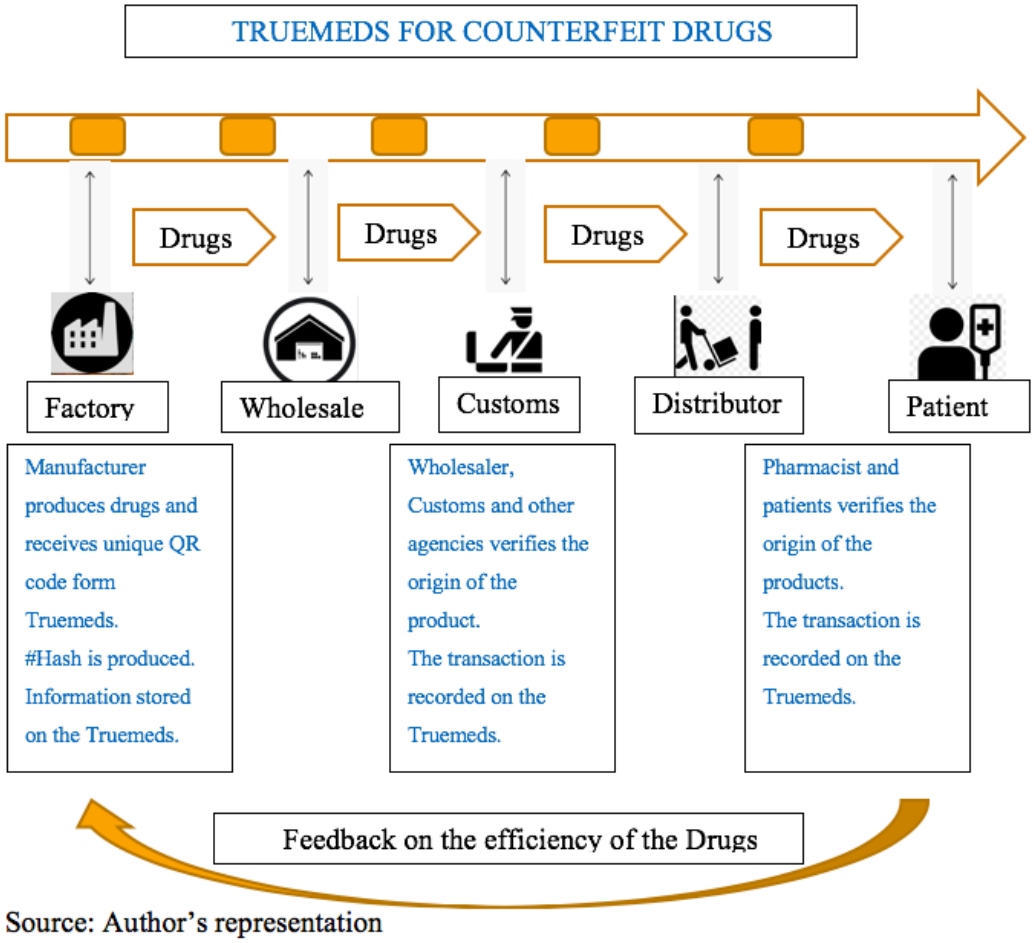
'Truemeds' – A Case Study

'Truemeds' is a blockchain enabled solution to counter the supply of the counterfeits developed by India based company Pipra Solutions Private Ltd.[50] to understand the case study, there is a need to understand the Blockchain technology architecture. As discussed from the above, Blockchain has a built-in identity mechanism, a cryptographically secure key pair to assign each participant in the network. A key pair consists of both public and private keys as it can be explained with the analogy of email, the email address can be treated as public key where everyone can send the information but to see the information a password is required which is similar to private key. And the participants in the pharmaceutical supply chain management will be manufacturers, wholesalers, shipping liners, customs authorities, distributors and doctors etc. who are identified with unique key pairs. On the network, drugs are treated as digital assets having a unique hash value which is generated after scanning of QR code or RFID tag or NFC tag.

The stakeholders in the supply chain might be adopting different Blockchain networks like Bitcoin, HyperledgerEthereum or BigchainDB and third-party APIs which pushes the data and transactions into the network. The interoperability of the Blockchain network is a different subject matter.

[50] '*Truemeds- Blockchain enabled counterfeit technology developed by Pipra Solution'*. See: https://truemeds.io

Truemeds is a blockchain enabled program set on a secured and trusted network wherein only trusted parties are given permission to enter the network. It is built on a user-friendly mobile application which even common patients can use it easily. Once the factory produces the



Source: Author's representation

product then truemeds will allocate a unique QR code and prints on the medicine. The unique QR code is assigned with a hash and transferred as a digital asset onto the Blockchain network and this hash can be traced any time on the network. If any additional information which is off no immediate use can be stored *off-chain* and with a hash digest (SHA 256) can be linked with the *on-chain* data. Since the drugs are registered on the Blockchain it will be easy for the transfer of ownership. For example, if a wholesaler wants to purchase the products from the manufacturer, the manufacturer will transfer the drugs physically to the wholesaler and physical transaction will be registered on the truemeds network. Similarly, it moves up on to pharmacists, doctors and patients etc. proving the authenticity of the drugs.

Truemeds unique mobile application will help doctors, nurses, family and patients easily verify the authenticity and the journey of the drugs from the manufacturer to pharmacy. the app is

also handy with respect to the customs authorities and other government agencies to enforce the IP law and to eliminate the counterfeits.

The benefits of the *'Truemeds'* include increased revenue, increased brand trust, reduced compliance risks, reduced operational expenses, faster and better inventory insights and increased supply chain efficiency.

CRITICISM AND CHALLENGES

Blockchain technology the most recognized trust related technology is also most untrusted technology among the skeptics. David Gerard is a vocal critic of Bitcoin and Blockchain as he is worried about the sheer number of scam artists and crooks surrounding the Bitcoin and the larger notion of the Blockchain.[51] Gerard is skeptical about the major technical and legal problems with the basic concept of a "smart contract", according to him the computer programs referred to as "smart contracts" are seldom either legal contracts or even particularly smart.[52]

David also criticises that at no extant blockchain can scale to the size of the data flow, "immutable" blockchains can't update to changes in ownership or laws and there are no consideration of security threat models.[53]

The major challenges of the Blockchain include data privacy and scalability.[54] The security of blockchain applications with an accent on the data confidentiality is an unsolved problem. So far, the blockchain ledger is implicitly public, but users demand more confidentiality for their data. On the other hand governments demand access to blockchain information for KYC policies and taxation.[55] The scalability problem has become vital, as the transaction rate growth made the designers think to increase the block size, which in turn might lead to higher network latency and vulnerability to various network attacks.[56] And the major difficulty for practitioners to decide whether or not to use blockchain is that limited product data or reliable technology evaluation available to assess the suitability of blockchains.[57]

Criticism and Challenges had drastically hit the Digital Transformation agency of Australia, it has gone cold on Blockchain after initial investment of $700,000 budget funding for the

[51] David Gerard, *'Attack of the 50 Foot Blockchain: Bitcoin, Blockchain, Ethereum & Smart Contracts'*.
[52] *Id.*
[53] *Supra* at 61.
[54] Sin Kuang Lo , Xiwei Xu , Yin Kia Chiam , Qinghua Lu, '*Evaluating Suitability of Applying Blockchain'* 22nd International Conference on Engineering of Complex Computer Systems (ICECCS), 2017.
[55] Alex Biryukov, *'Security, Scalability and Privacy in Blockchain Applications and Smart Contracts'* 2018.
[56] *Id.*
[57] *Supra* at 64

investigation of the technology.[58] According to DTA chief digital officer Peter Alexander, it is *"an interesting technology"* that is *"well worth being observed"* but without standardisation and a lot more work, for every use of blockchain that you would consider today there is a better technology such as databases and APIs.[59] He added that "Blockchain is good for low trust engagement – you don't know who you're dealing with but have a series of ledgers that can give some validation and support" and it's mostly large tech companies that are driving the hype for blockchain, rather than governments or users.[60]

It is the fact that the above criticism and challenges are real and the Blockchain industry is working out the solutions to overcome the problems. In the case of data protection, the private immutable ledger data has become compatible with EU data protection policy.[61] And DTA criticism is largely related to standardization rather the technical nature of the Blockchain. WIPO patent analysis from the above clearly depicts that Australia is one of the leading nations in the world when comes to Blockchain patenting.

CONCLUSION

Blockchain can certainly be a technological solution to fight the counterfeits. With respect to overall elimination of the counterfeits, other aspects need to be considered such as increasing customer awareness and creating user friendly apps for the customers to easily verify the authenticity of the products, establishing the strong legal mechanisms, proper alert systems and most importantly using the tamper proof packaging.

In the stack of present technologies, blockchain is the important technology to fight the counterfeits. but when it is combined with IoT and Artificial intelligence it can become a deadly weapon to eliminate the counterfeits. Blockchain based drug supply chains are shifting the traditional governance model from government regulatory mechanisms like auditing and inspection to surveillance by all the stakeholders in the supply chain.

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[58] Denham Sadler, '*DTA goes cold on Blockchain'* OCTOBER 23, 2018. https://www.innovationaus.com/2018/10/DTA-goes-cold-on-blockchain

[59] Rohan Pearce, *'Blockchain What is it good for? At the moment not much, DTA says'* OCTOBER 23, 2018. https://www.computerworld.com.au/article/648615/blockchain-what-it-good-moment-much-dta-says/

[60] Sadler, *Supra* at *68.*

[61] Jemima Kelly, *'Immutable ledgers meet European Data Protection'* Financial Times, 12 April 2018. https://ftalphaville.ft.com/2018/04/12/1523503800000/Immutable-ledgers-meet-European-data-protection-/