Elements of Resilience to Combat Counterfeit Medicines in Supply Chain

Flávia Renata Pinho de Lima (flaviarelima@gmail.com)
Universidade Federal de São Carlos (UFSCar)

Andrea Lago da Silva
Universidade Federal de São Carlos (UFSCar)

Moacir Godinho Filho
Universidade Federal de São Carlos (UFSCar)

Eduardo Mario Dias
Universidade de São Paulo (USP)

Abstract

The purpose of this study is to understand how elements of resilience influence the combat of counterfeit medicines. After a literature review, an empirical research – case study - was performed. The case study shows two medicines supply chains work across its boundaries to combat counterfeits. It also enabled a deeper investigation of the elements of resilience and counterfeit anti-measures applied. According to case studies, collaboration, trust, visibility, information sharing and sensing are the most relevant elements to combat medicine counterfeiting. The main contribution of this study is to discuss how these elements are relevant for increasing resilience to counterfeit medicines.

Keywords: supply chain, elements of resilience and counterfeit medicines.

Introduction

Intellectual property (IP) is an intangible and valuable asset used by organizations to leverage competitiveness and, therefore, has become a key-factor in organization evaluation (Green & Smith, 2002 and Staake et al., 2009). One of the threats to IP is counterfeit, which means trade products that bear reference to a brand or organization without authorization and could be confused with an original one (Staake et al., 2009).This study focus on counterfeit of medicines, motivated by the nature of counterfeiters operation (Stevenson & Busby, 2015) and, more specifically in medicines because of the criticality of threats in healthcare (Cockburn et al., 2005) and the amount of incidents in healthcare and difficulty to identify counterfeit products (Stevenson & Busby, 2015). In Brazil, where the case study is performed, counterfeiting has been largely discussed due to a new legislation, aimed at implementing a traceability system (Nogueira & Vecina Neto, 2011), and investments from organizations and government to increase supply chain security.

Authors claim that the more resilient the supply chain, the greater the trend of better respond to disturbances (Brusset & Teller, 2017). Thus, one opportunity to mitigate counterfeit risk is the development of resilience into supply chains. For the purpose of this study, Supply Chain Resilience (SCR) represents the supply chain's adaptative capability to prepare and adapt to respond positively to changes and disturbances in operations (Brusset & Teller, 2017; Kamalahmadi & Parast, 2016) and evolve to a new operating state (Ali et al., 2017; Christopher & Peck, 2004; Fiksel et al., 2015).

A few authors have dedicated to study specific disturbance scenarios, (e.g. Rashid, et al., 2014 and Scholten et al., 2014). However, despite the recent acknowledgment of counterfeit as a supply chain risk source, we identified a single study - Stevenson & Busby (2015) - that explicitly links SCR elements and counterfeit anti-measures. They identified four sets of strategies used by counterfeiters to introduce illegitimate products and proposed anti-measures to increase resilience. Thus, this gap in the literature, namely the lack of understanding in how elements of resilience may contribute to increase resilience to counterfeits, is the motivation of this research. Our objective is to understand how elements of resilience influence the combat of counterfeit medicines.

The remainder of this paper is structured as follows. Section 2 shows the results of a systematic literature review where 16 *counterfeit anti-measures and* 13 elements of resilience could be identified. Section 3 presents the research method used in the empirical research. Section 4 summarizes the main findings of the case studies and a counterpoint comparison with literature is drawn. Section 5 summarizes the findings and presents the main conclusions of this study. Finally, Section 6 presents new opportunities of research and limitations of this study.

Literature Review

A literature review was performed in this paper considering articles published over the last 15 years from 2002 to 2016. The review included databases Web of Science, Scopus and ProQuest, using the key-words ("counterfeit*"), ("supply chain*"), ("resilien*"), ("risk*"), ("medicine*") and/or ("pill*").

The findings of the literature review respond which are the counterfeit anti-measures and elements of resilience discussed by the authors. The review raised 16 anti-measures, divided into four groups:

- inter-organizational processes and policies: strict government requirements, enforcement of IP rights, Enhance national and international cooperation and monitor supply chain members;
- intra-organizational processes and policies: R&D strategies, price strategies, create an internal structure, improve quality and supply/partner strategies;
- behavioral: enhance risk awareness, enhance brand reputation, standardize and train practices and processes and train members to identify fakes; and
- technology: traceability, authentication technologies, big data & analytics.

Moreover, we mapped and conceptualized 13 elements, presented in Table 1.

Table 1 – Definition of elements of resilience identified in the present literature review

Elements	Definition	Authors
Flexibility	The ability of a firm and supply chain to sense threats, react, and adapt to changing requirements with minimum time, effort, cost and performance drop.	Rashid et al. (2014); Soni et al. (2015); Tukamuhabwa et al. (2015)
Redundancy	Replication/Addition of capacity and/or resources that can be invoked during a disturbance to replace the loss of capacity and/or resources during a disturbance.	Soni et al. (2015); Tukamuhabwa et al. (2015)

Collaboration	The ability to join efforts and work effectively within an organization or with other supply chain entities for mutual benefit. In the context of resilience, it reinforces the importance of internal and external communication.	Ehrenhuber et al. (2015); Scholten et al. (2014); Soni et al. (2015); Tukamuhabwa et al. (2015)
Trust	Relationship of trust among supply chain members, a critical component in building successful long-term relationships	Kamalahmadi & Parast (2016); Papadopoulos et al. (2016)
Information sharing	Share important and possibly proprietary information among supply chain members and inside organizations.	Papadopoulos et al. (2016)
Information security	Secure information communicated inside the firm with supply chain partners and other stakeholders against deliberate intrusion or attacks.	Rajesh; Ravi (2015)
Agility	The ability to react and adapt quickly to changes and potential or actual unpredictable events.	Christopher & Peck (2004); Scholten et al. (2014); Tukamuhabwa et al. (2015)
Visibility	The ability to transparently see through all supply chain links to reduce the information asymmetry, quickly identify needs and disruptions and be able to implement changes in an effectively.	Christopher & Peck (2004); Ehrenhuber et al. (2015); Tukamuhabwa et al. (2015)
Sensing	The ability of discerning processes ahead of time and anticipating potential future events or situations.	Ehrenhuber et al. (2015)
SCR culture	Infusing a culture of resilience and risk awareness to make it the concern of everyone.	Christopher & Peck (2004)
Leadership	Commitment and support of top managers to implement and maintain SCR.	Kamalahmadi & Parast (2016)
Innovation	Reach beyond the organization's boundaries and strive to continuously transform knowledge and ideas into new products, processes and systems for the benefit of the supply chain.	Ehrenhuber et al. (2015)
Reengineering	Redesigning the supply chain considering certain characteristics to build resilience, reduce risk exposure and overcome disruptions.	Christopher & Peck (2004); Scholten et al. (2014)

Source: created by the authors

Research Methodology

The empirical method chosen in this study was case study, often used in Operations Management (Voss et al., 2002) to pursue an explanatory purpose (Yin, 2015). In addition, the method enables the phenomenon (counterfeiting in medicine supply chain) study in its real context, the deep understanding of phenomenon complexity and nature, the investigation of cause and effect relationships (the role played by elements of resilience), and expansion of research horizons (Fawcett et al., 2014) (how resilience and counterfeiting mitigation could be related).

Following the guidelines drawn up by Baxter and Jack (2008) and Yin (2015), the first step in a case study is to define the unit of analysis. In this study, it is the set of elements of resilience that combat counterfeit within the pharmaceutical focal company and key supply chain links from the downstream product flow. This study identified two relevant pharmaceutical focal companies and four members from downstream flow in supply chain that accepted participate in this empirical study, as observed in figure 1.

To deep the understanding of phenomenon complexity and nature, during this research, nine other entities and associations, representing the 5 entities that work through all supply chain were interviewed to increase validity of the data and understand how they affect the fight against counterfeiters. Figure 1 summarizes the organizations involved in the empirical research.
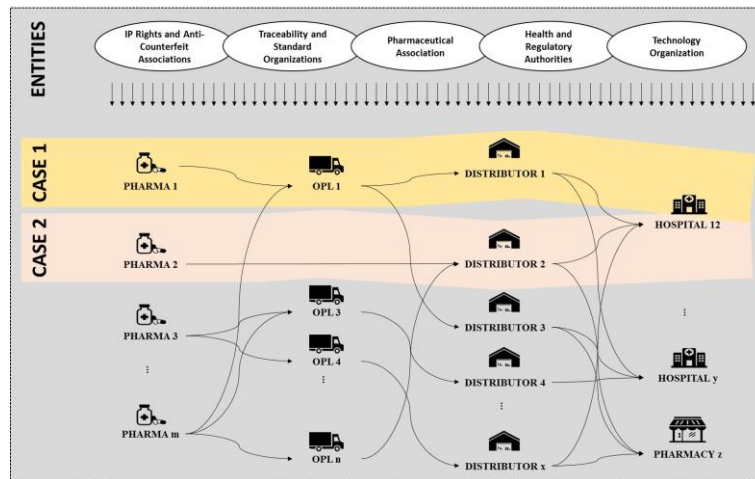
Figure 1 – Medicines supply chain links and case studies selected
Source: created by the authors

Tables 2 and 3 present details of the organizations and entities studied.

Table 2 – Characteristics of cases 1 and 2

Case	Pharmaceutical company	Third-party logistics company	Medicines distributor	Hospital
CASE1	PHARMA1 is a multinational organization with approximately 100 thousand employees working in more than 150 countries.	OPL1 is the single-medicine logistics provider of PHARMA 1. The organization is a large American company with operation in most of countries around the globe.	DISTRIBUTOR1 is one of the main clients of PHARMA 1. The organization is one of the biggest Brazilian's distributors focused on pharmaceutical sector.	HOSPITAL 1/2 has a history of purchases from DISTRIBUTOR 1 and DISTRIBUTOR 2. The organization is a famous public hospital in São Paulo State.
CASE2	PHARMA2 is a well-known national pharmaceutical company with more than 2.000 employees and a large medicines portfolio	-	DISTRIBUTOR 2 is one of the organizations responsible for distributing the products of PHARMA 2.	

Source: created by the authors

Table 3 – Characteristics of studied entities that affect both cases

Entity Objective Regarding Counterfeit/ Resilience	Main characteristics	Interviewees and Roles
Association Focused on IP Rights and Counterfeit Combat	CROSSASS1 aims at developing the economy and strength business. One of its goals is improve enforcement of IP rights in Brazil	AIPrep1 (Association's Representative)
	CROSSASS2 is an association of companies that aims at fighting illegal activities that harms Brazilian business	AIPrep2 (Association's Representative)
Organization Focused on Traceability and Standard Definition	CROSSORG1 focus on developing and disseminating best practices to improve Logistics	Orep1 (Organization's Representative) and OTRACrep1 (Traceability Representative)
	CROSSORG2 is responsible for developing and disseminating best practices involving medicines	OTRACrep2 (Traceability Representative)
Pharmaceutical Association	PHARMAASS1 is an association of pharmaceutical companies in São Paulo State	PArep1 (Association's Representative)

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	PHARMAASS2 is an association of national and international pharmaceutical companies	PArep2 (Association's Representative)
Health and Regulatory Authorities	ANVISA is a federal health regulatory body of the Brazilian government	ANVrep (Representative of products controlling)
Technology Organizations	TECORG1 is a group of researchers that works in the areas of research and development of automation and process redesign	TOcoord (Coordinator), TOcoordtec (Technical Coordinator) and TOres1 (Researcher)
	TECORG2 is an automation engineering company, responsible for studying innovative solutions to integrate and promote communication between traceability systems	TODoper (Director of Operations) and TODred (Director of R&D)

Source: created by the authors

Results and data analysis of case study

General Actions Taken in Case 1 and 2 about Counterfeit
We identified all counterfeit anti-measures raisin literature review (see Table 1) in at least one organization from cases 1 and 2. The two anti-measures groups most used by organizations from case 1 to mitigate counterfeit risks are technology and inter-organizational processes and policies. Authentication technologies and big data & analytics are applied in different levels by all organizations of cases 1 and 2, and traceability just was not mentioned by OPL1. Thus, they are investing in technologies to mitigate counterfeit risks. Authentication technologies are in constant evolution and, develop overt and covert solutions to identify falsified medicines is crucial to the supply chain. On the other hand, the implementation of traceability and big data & analytics still demand many improvements to truly boast the benefits of both systems, once the application in the companies is in the early stages of maturity in comparison to other companies from different sectors.

Moreover, it is consensus in both cases that the development of inter-organizational processes and policies anti-measures is also crucial to address the counterfeit threat. Data collected shows that, for measures that exceed the internal boundaries, organizations tend to transfer the responsibility of combatting counterfeiters to Anvisa and other associations that they are affiliated, to avoid being associated with this disruption.

Nonetheless, pharmaceuticals companies tend to have a more proactive approach against counterfeiters, once they possess the brand of the medicine and counterfeit incidents may damage the organization's image. Willing to protect the brand, both pharmaceutical companies created internal teams to investigate counterfeiters and highlighted the necessity of having a **hotline to help patients**, where consumers may call whenever they have doubts about the products purchased or fell there is something wrong with it. This counterfeit anti-measure was not previously identified in literature review.

We observed that other intra-organizational processes and policies anti-measures were not previously identified in literature review such as: (i) **investing in security equipment and systems** to detect risks associated to counterfeiting. The interviewer PMgenlatam1 stated that it becomes even more important when dealing with more sophisticated products, with high aggregated value. Examples of this anti-measure are investments on warehousing management system (WMS), transportation management system (TMS), routing system and high technology equipment to transport, store and track products. OPL1 and DISTRIBUTOR1 also invest lots of money to increase the safety of its logistics operations. (ii) PHARMA2 also cited the relevance of having **reverse logistics capabilities**. Medicines dispensed without correct procedures may became an "easy opportunity" for counterfeiters, because they can easily reuse the package or resell the

pills, which may have expired, for example. Recall of medicines may also be necessary and is a major undertaking, requiring complex logistics. When the government decides to recall a product, all supply chain should be prepared to pick the product and record data. PHARMA2 and HOSPITAL12 have their own structure to dispense the medicines not consumed and the secondary package.

Furthermore, the meaning of **standardize and train practices and processes** was expanded to more accurately represent its content. The anti-measure encompasses practices and processes and train supply chain personnel to handle counterfeit issues. However, as pointed out in the data gathered, more than learning how to handle the incidents, standardized practices and processes may be applied with three other goals. (i) First, to avoid incidents from happening. For instance, PSqualsec2 stated that risk management practices and policies are established along with Insurance and Risk Manager Organizations. (ii) Second, to mitigate the losses during counterfeit incidents. DISTRIBUTOR2, for instance, limits the value that may be transported in the same vehicle to minimize losses in case of theft. (iii) Third, to help consumers to deeply know the characteristics of their medication and easily identify when something is not in place. Thus, we propose that this anti-measure be denominated **standardize policies, practices and processes** and encompasses the definition, implementation, enforcement and training of standard policies, practices and processes addressed to mitigate risks associated to counterfeiting.

Train customers to identify fakes become a sub-item of a broader anti-measure, with the objective of **empower consumers to combat counterfeits.** That means training consumers, but also providing tools to help them identify and report incidents without external help. Thus, make consumers auditors of medicines supply chain. PHARMA1 website, for example, encourages consumers to recognize their medication and be familiar with its features. PHARMA2 does not apply this anti-measure.

On the other hand, although widely discussed and controversial in literature concerning mitigation of counterfeit risks (see Cho et al., 2015, Green & Smith, 2002 and Qian, 2014), the counterfeit anti-measures **improve quality** and **price strategies** were not identified in case 2. Moreover, they controversial in case 1. Interviewees from case 1 state that quality and price is mostly established by Anvisa, thus, they must follow the regulation and there is no margin for making changes. However, brochures from PHARMA1 state that "the price of the product X is high, be wary if you find prices to appealing". Thus, in the discussion raised in literature review concerning setting low or high prices strategies, PHARMA1 follows the suggestions proposed by Qian (2014) and Cho et al. (2015), who argues that elevated prices help consumers to distinguish the brand from counterfeiters. Despite these efforts, we did not identify any evidences that PHARMA1 control the prices charged by other supply chain members downstream.

Role of Elements of resilience in Combatting Counterfeit Medicines
In both cases interviewers believe that counterfeits take advantage of the complex network of distributors to insert illegal products into legal medicines supply chain. This complex network is leveraged by a characteristic of Brazilian medicines supply chain, because distributors tend to sell medicines to other distributors and not direct to hospitals and/or pharmacies. Few distributors sell just directly to pharmacies and/or hospitals. PMtec1 state "we calculate that the medicines change custody six times before consumption". This characteristic increases the difficulty of controlling supply chain and ensuring the authenticity of medicines traded. HMpurlog12 highlighted the difficulty of assuring that the medicine purchased is legal when buying from a distributor, once it is

not easy to associate through documents the medicine to its original pharmaceutical producer.

PHARMA1 focus on promoting counterfeit anti-measures directed at patients. However, the interviewees state that this action has to be a careful process once is forbidden for pharmaceuticals to advertise their medicines in Brazil. PHARMA2 has been struggling to monitor the sales of its products from online pharmacies. According to PMrisk2, the consumption from these sources has been growing fast in recent years; however, the control of these distributors is complex because of the size of World Wide Web and the difficulty to track the website owner. Cases of consumers asking about products on internet with specifications different than the one produced by the pharmaceutical (e.g. liquid instead of pill) has become more frequent.

From the data gathered and the content analysis performed, this research was able to analyze how the organizations studied use the elements of resilience to increase its resilience to counterfeiting. Cases 1 and 2 present many similarities. Although in different orders of priority, both cases consider **visibility, trust, collaboration, sensing** and **information sharing** as elements of resilience most often associated with counterfeit anti-measures. Moreover, data collected from both cases shows the importance of regulatory associations and other national and international entities to counterfeit combat. First, data gathered shows that organizations from cases 1 and 2 rely mainly on Anvisa's regulations to make decisions about investments to increase resilience to counterfeiting.

This strategy is similar to medicine supply chains in other countries such as the United States, as reported by Coustasse et al. (2010). ANVrep reinforces the necessity of enhancing **supply chain visibility** to better prepare and deal with counterfeit incidents. Visibility enables Anvisa to support the development of **strict government requirements/laws** and its **enforcement**, and to **monitor the supply chain**. Moreover, Brazilian organizations also understand that a more comprehensive outcome of these initiatives is achieved when there is cooperation among national and international entities involved in counterfeit combat, as demonstrated by Almuzaini, Choonara and Sammons, 2013 and Coustasse et al., 2010. For instance, data showed that better results are achieved when visibility is associated with collaboration. "For example, nowadays thefts reported in our ports and board may trigger joined actions among Anvisa and Federal Policy, which help us to solve the crimes" (ANVrep).

However, it is worth mentioning that although literature review has addressed trust in relation to consumers (Cesareo & Stöttinger, 2015; Lybecker, 2008) and other supply chain members (Lybecker, 2008), few has been said about trusting in the government and regulatory agencies. Interviewees from cases 1 and 2 state that **trust** is crucial for the relationship between Anvisa and the organization participating in the medicines supply chain.

Furthermore, PHARMA1 and PHARMA2 have local teams to help during investigations. As counterfeits usually work globally and are dangerous, dealing with incidents is usually responsibility of police offices. PHARMA1, as a multinational company, has also a global structure to investigate counterfeit incidents. This helps organizations to minimize global sourcing vulnerability (Rashid et al., 2014). In addition, both organizations, as all the others studied in this project, join national and/or international associations to defend their needs and conduct investigations about counterfeiters. Most of the combat actions that crosses the organization`s borders are carried out by these associations and the government.

The main difference between both cases is the focus given by the company to increase resilience to counterfeit. PHARMA 1 has promoted anti-measures directed at consumers focusing on **empower consumers on counterfeit combat** and **increase risk awareness**

mostly by encouraging them to buy from reputable sources and sharing information about how to identify fake products. Such anti-measures have not been identified in case 2.

When asked, interviewees from PHARMA2 state that consumers will have a better visibility of counterfeited medicines with implementation of traceability, because they will be able to consult if the package ID is trustable. Thus, they argue that PHARMA2's role is to focus in developing internal solutions that will increase security of their processes and their downstream companies' processes, and support Anvisa to increase consumers' awareness.

Despite these efforts and different approaches of anti-measures directed at consumers, it is worth mentioning that, although these initiatives empower consumers to identify suspicious products, they focus just on one of the two market scenarios proposed by Grossman and Shapiro (1988a, 1988b). As their goal is to help consumers to identify counterfeited products, they are directed at deceptive counterfeiting – i.e. when consumers are unaware that they are not purchasing original products and cannot detect them by inspection or inference from place of purchase. However, unlike common sense, the other type of trade also applies to the medicines supply chain: the nondeceptive counterfeiting, when consumers know or strongly suspect when they purchase not original products. Thus, the demand for nondeceptive counterfeiting mainly exists for consumers to buy medicines without prescription or because of the high price of the medicines, which may be find cheaper in internet, for instance. To combat this market scenario and to leverage the benefits of deceptive counterfeiting as well, organizations should focus on increasing SCR culture against counterfeiting. However, as stated by Cesareo and Stöttinger (2015), the use of consumer-direct anti-counterfeit measures depends on how open, transparent and proactive an organization is willing to be about this sensitive subject with its clients. During all interviews and data gathered, we could notice that talking about counterfeit medicines is still a taboo in the medicines supply chain. Nonetheless, CROSSASS2 was the only association to openly address the problem and develop brochures and merchandising to explain the impact of counterfeited products.

Conclusions

The theoretical and empirical research performed in this project present insights on how the medicine supply chain may strength its elements of resilience to better deal with counterfeit disruptions. In both cases, the pharmaceutical company is primarily responsible for defining the approach taken by the supply chain against counterfeiters. Besides the health problems to the patients, as they possess the brand of the medicine, counterfeit incidents mainly damage the image of the pharmaceutical, which explains their higher interest in mitigating this threat. Nonetheless, as the concern of the pharmaceuticals increase, organizations downstream have to adapt and enhance security to maintain its reputation and continue to have the permission to buy from the manufacturer. Moreover, all organizations rely on Anvisa and other national and international entities to fight for more strict regulations and ensure enforcement of existing laws.

The main elements of resilience applied by the case studies and in accordance with the literature findings were **visibility**, **trust** and **collaboration** (Christopher & Peck, 2004; Ehrenhuber et al., 2015; Kamalahmadi & Parast, 2016). The data analysis frequently identified these three elements as the most often cited and most associated with counterfeit anti-measures. By combining them, organizations focus on monitor and control the supply chain, promote enforcement and enhance cooperation. For that, they create internal teams specialized in dealing with quality and/or security issues related to counterfeit and define rigorous policies for suppliers and partners. Although the strategies

are similar, the study identified relevant differences regarding the approach of both cases. Case 1 is influenced by PHARMA1, a multinational pharmaceutical company. Thus, most of the strategies are global and performed by international teams that collaborate with governments overall. Therefore, case 1 seems to have more power and ability to combat the counterfeit threat from an external perspective, as counterfeiters also work globally and a holistic perspective is necessary to investigate them. Furthermore, data gathered showed many initiatives to empower consumers to fight counterfeits. On the other hand, organizations from case 2 have just local influence and, therefore, have limited ability to investigate counterfeit incidents. Most of the anti-measures focus on increasing security among its supply chain links downstream, not including the consumer or patient, and invest in security equipment and standard procedures. Moreover, PHARMA2 has been developing **innovative** solutions, such as traceability and investment in bio similar medicines, which increase resilience to counterfeiting.

Additionally, data analysis raised **information sharing** and **sensing** as elements of resilience highly associated with counterfeiting threat and that the impact has been growing in recent years boosted by the possibility of combining a huge amount of data from several sources. Although still in its infancy, both cases have been using big data & analytics solutions to gather information available from traceability and security systems and use them to improve the decision-making process before and after a counterfeit disruption. Another relevant finding of this research is that the absence of collaboration and information sharing are barriers to increase resilience to counterfeiting. The lack of collaboration among the supply chain difficulty the implementation of the medicine traceability system, responsible for increasing supply chain visibility. The lack of information sharing between organizations and other sources seriously reduces the capability of the big data & analytics systems, as their relevance is built on the ability of combining data from different sources and trigger actions to avoid or mitigate incidents. Therefore, the lack of collaboration and information sharing suppress the supply chain resilience to counterfeiting.

Although this research promotes some advances on how elements of resilience may mitigate counterfeit risks, more studies are needed to evaluate the applicability of these findings in different sectors, countries and types of companies. On the other hand, this paper discussed the role of elements of resilience as barriers, and not facilitators, to prepare and respond for disruptions. These findings may influence how organizations should prioritize and focus its efforts to increase resilience to counterfeit.

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