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NanoLuxe: a market analysis, pricing policy and regulatory affairs for an anti-counterfeit company based on nanotechnology

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Summary/Abstract

Counterfeit is an ever-present phenomenon that involves making illegal copies of valuable items with the intention of making profit from their transactions. The vulnerabilities in the supply chain of medical devices have set the ground for these criminal groups to target the medical industry. Substandard and unauthorized medical products are currently in the market, putting millions of people at risk and being a serious threat to public health. NanoLuxe is a company that is developing a system to label and identify products with barcoded-nanoparticles, guaranteeing the traceability and authentication of goods down the supply chain. A market analysis is performed in order to evaluate whether this business could be profitable in the medical devices industry. With the information gathered in the market analysis and the definition of a clear market niche, a pricing policy and strategy is carried out. Accordingly, this is accomplished by analyzing the level of competition, the supply and demand curves, the scalability of the sector and the cost-effectiveness of the technology. Furthermore, the regulatory affairs that this technology requires at an European level and under the FDA (Foods & Drugs Administration) regulations are assessed.

Keywords

Anti-counterfeit, Medical devices, Pharmaceuticals, Supply chain, Market analysis, Pricing policy, Pricing strategy, Regulatory affairs

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Preface or prologue

Nanoluxe is a new company that aims to fight counterfeit of luxury goods by implementing a new cutting-edge nanotechnology. Their research on the subject has lead them to the development of an un-copyable ink-based tracking nano-platform. The particles that constitute the ink give a unique signal that can be rapidly (≤2 seconds) measured with a handheld optical reader. The bicompatible ink enables the application of the Nanoluxe technology to the medical field.

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1. INTRODUCTION

1.1 A global outlook to counterfeit

The establishment of an innovation-driven economy worldwide has given rise to the reinforcement of Intellectual Property Rights (IPR) to promote market growth. Modern industries use IPR to generate value within very competitive landscapes and governmental organizations rely in IPR to drive sustained economic prosperity in their respective countries. IPR have enabled markets to expand their scopes by investing in advanced technologies without the fear of being extorted. These type of activities remarkably stimulate the creation of new jobs and thus, they are rewarded and promoted to increase business and government revenues, investment and innovation, and economic growth. As stated in a 2013 study performed by the European Patent Office (EPO) and the EU Intellectual Property Office (EUIPO), approximately 39% of all economic activity and 26% of all employment in the European Union is entirely achieved by IP-intensive industries.[1] IP rights provide a legal protection for original works, inventions, appearance of products and scientific developments, amongst others. The infringement of these rights results in a reduced wealth creation that ultimately harms the Gross Domestic Product (GDP).

However, the harm goes beyond the economic issue as it also negatively affects the consumers that are provided with goods that are not in compliance with health and safety standards. The word counterfeit is tightly related with IP rights violations. Counterfeiting is a global phenomenon that involves making illegal copies of valuable items with the intention of making profit from their brand image. These products are replicas that are unauthorized which means that they have not been regulated according to the legal framework. They often contain the logos and brands of legitimate firms which results in patent and trademark infringements.With the boost of globalization, the creation of new and facilitated trade routes has set the ground for the increase of these illicit trade activities. IP rights infringements have become a major challenge for our global economy, since they negatively affect both corporate entities and the individuals.

According to the OECD and the EU's Intellectual Property Office 2019 report on *Trends in Trade in Counterfeit and Pirated Goods*, the value of imported counterfeited and pirated goods in 2016 amounted $509 billion which represents 3.3% of world trade. This report also stated that 6.8% of EU imports from third countries are known to be of deceitful origin. Goods infringing intellectual property rights are gradually increasing in the EU market because of the growing number of online purchases in Europe. The development of new forms of marketing such as e-commerce has led to this higher incidence of fake online goods.

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[1]European Patent Office, & European Union Intellectual Property Office. (2019). IPR-intensive industries and economic performance in the European Union. *European Union Intellectual Property Office* .

For many years it was thought that counterfeiting was a static activity that only occurred in targeted industries, the most common one: the textile industry. Although, the truth is that, counterfeiting has always been changing and adapting to the conditions of global trade. Nowadays it has become so profitable that it constitutes a major global industry itself. Criminal groups traditionally engaged in the sale of luxury and branded goods as well as pirated digital content. Nevertheless, counterfeiting has diversified from long-established activities towards new and highly profitable sectors. The industry affected the most by counterfeit is still the textile including footwear, clothing and leather goods. Following this industry, the spare parts of electrical components, watches, medical equipment, perfume and cosmetics, toys, jewelry and pharmaceuticals are the most common targeted products.[2]

Top counterfeit products globally by industry

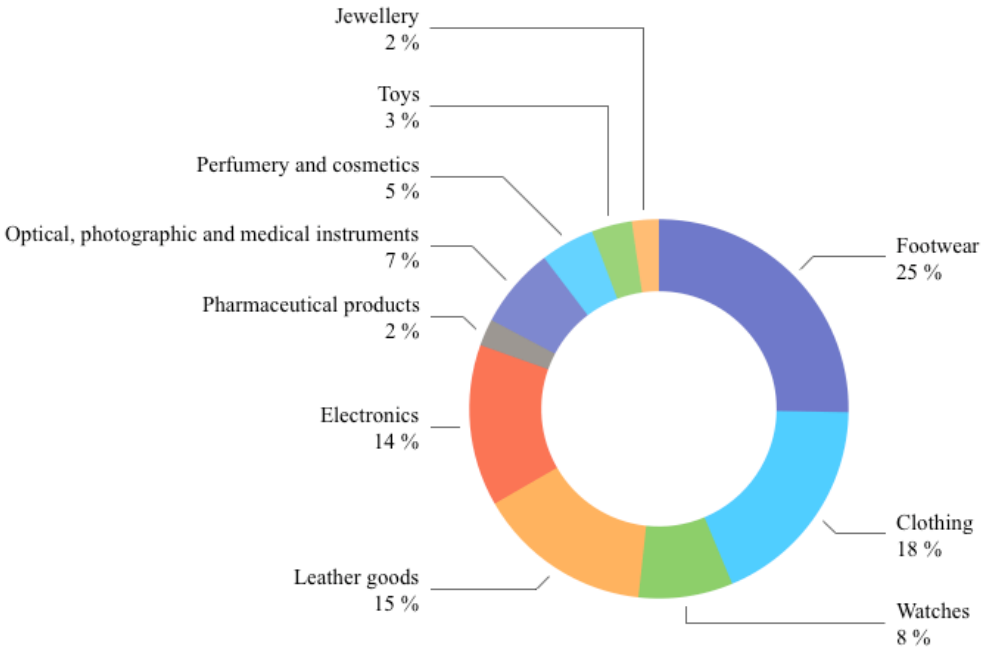

Figure 1: Top counterfeit products globally by industries

The Global Brand Counterfeiting Report from 2018 revealed that luxury brands lost approximately 98 billion dollars due to counterfeiting in 2017. About 30.3 billion dollars from the total losses of the high-end consumer goods sector were due to online counterfeiting. This study also estimated that the revenue losses by 2020 would reach

[2]OECD/EUIPO (2019), Trends in Trade in Counterfeit and Pirated Goods, Illicit Trade, OECD Publishing, Paris/*European Union Intellectual Property Office*. https://doi.org/10.1787/g2g9f533-en

1.82 trillion dollars. The industries of luxury goods acknowledge this worldwide issue and spend a colossal amount of money protecting their brand and trademarks.[3]

Private companies experience the effects of these clandestine activities in their sales revenues, profit margins and reputation. One of the main goals of companies is to be considered trustworthy and honorable by their consumers while providing the exclusivity they are seeking for. With the rise of counterfeited products, businesses are constantly losing liability and this constitutes a serious threat for any brand or business, even for long-established ones. In addition to this, the counterfeit enterprises do not have to undergo the R&D investment, giving them an extra competitive advantage. The legitimate brands have to face the additional costs for conducting investigations to protect their IPR against wrong-doers. For instance, the french brand Louis Vuitton spends 17 million dollars annually on anti-counterfeiting legal action, with more than 60 lawyers specialized in these matters. However, these efforts are not having a tangible effect since the numbers of counterfeited goods are increasing even more each year.[4]

1.2 Counterfeit in the medical products and pharmaceutical industries

Medical innovations have an enormous impact on society and economic growth as they are crucial to seal the gaps in global healthcare provision. These innovations are occurring across multiple fields of the medical industry, including drug development. The pharmaceutical industry has always been an IP-intensive field with numerous patents. During this last decade, there has been a notable decline in pharmaceutical R&D productivity and a longer process for expanding health innovations worldwide due to the complexity of the health ecosystems. Nevertheless, the combination of digital and biological technologies has led to the development of new medical technologies with the potential to disrupt healthcare, and thus, the number of patents developed for medical technologies has surpassed that of the pharmaceutical industry. According to the World Intellectual Property Organization (WIPO), the number of trademarks applications for the pharmaceutical industry represents around 4.3% of all world trademark applications, making it the fourth most IP-intense industry worldwide. Aside from IP, the medical and pharmaceutical industries are some of the most research intensive, accounting for more than a 22% of all total R&D across all industries in 2018.

Withal, pharmaceuticals and medical devices are quite vulnerable to counterfeiting. In terms of pharmaceuticals, around 0,84% of total world-wide imports in pharmaceutical products are estimated to be counterfeit goods according to the OECD/EUIPO (2019) study. In the pharmaceutical industry the EMA (European Medicines Agency) defines a counterfeit pharmaceutical as a *medicine made by someone other than the genuine*

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[3]ltd, R. and M. (2017, December). *Global Brand Counterfeiting Report, 2018*. Research and Markets. https://www.researchandmarkets.com/reports/4438394/global-brand-counterfeiting-report-2018.

[4]Organisation for Economic Co-operation and Development. (1998). The Economic Impact of Counterfeiting. *OECD*.

manufacturer, by copying or imitating an original product without authority or rights. Hence, counterfeit medicines disobey the trademark law.

The types of pharmaceuticals that are most targeted by these criminal groups is alarming, as they pose a serious threat to the health and well-being of the most defenseless collectives. Over the period of 2014-2016 a considerable amount of confiscated counterfeit pharmaceuticals included medicaments to fight malaria, HIV/ AIDS and cancer. In further detail, the most falsified medicines were antibiotics, lifestyle drugs and painkillers. Following these, the most seized counterfeit medicines were those included in the treatment of malaria, diabetes, epilepsy, heart diseases, allergy, blood pressure, cancer, stomach ulcers ailments and local anesthetics.

The IP right holders most affected by these counterfeit medicines over the period of 2014-2016 are US brands, followed by European economies such as Switzerland, United Kingdom (UK), Germany and France. On the other hand, the countries that manufacture most of these counterfeit medicines are India (53%), China (30%) and United Arab Emirates (4%). The EUIPO estimates that the pharmaceutical industry loses approximately €10.2 billion of revenue annually due to counterfeiting in the EU marketplace, corresponding to 4.4% of the sector's total sales.[5]

Counterfeit in the trade of pharmaceutical products and medical devices is a significant and growing safety threat to healthcare and patients. The World Health Organization (WHO) is mindful of the impact of counterfeit and it has recognized this matter to be one of the most urgent to resolve this upcoming decade. The WHO estimated that one in ten medicines in low- and middle-income countries are classified as substandard or falsified. Furthermore, the percentage at a global level of counterfeited medical devices and in vitro diagnostics (IVDs) that are in circulation was estimated to be 8% in 2013, being this number expected to be higher today.[6] Additionally, the WHO has made the effort to classify medical products that do not follow the adequate legal pathway as:

- **Substandard:** Also called "out of the specification", these are authorized medical products that fail to meet either their quality standards or their specifications, or both.
- **Unregistered/unlicensed:** Medical products that have not undergone evaluation and/or approval by the NRRA for the market in which they are marketed/distributed or used, subject to permitted conditions under national or regional regulation and legislation.
- **Falsified:** Medical products that deliberately/fraudulently misrepresent their identity, composition or source.

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[5]OECD/EUIPO (2020), Trade in Counterfeit Pharmaceutical Products, Illicit Trade, OECD Publishing, Paris, https://doi.org/10.1787/a7c7e054-en.

[6]World Health Organization. (2020). *Substandard and falsified medical products*. World Health Organization. https://www.who.int/health-topics/substandard-and-falsified-medical-products#tab=tab_1.

The counterfeit of medical devices and equipment is less reported and widely accepted than that of pharmaceuticals. Nonetheless, over the years there have taken place several scandals regarding the quality of some medical equipment and devices that have brought this issue to the light. One of the most famous cases was the Poly Implant Prothese (PIP) breast implants that were made with sub-grade silicone gel that was cheaper and meant for industrial and not medical use. More than 500,000 women in 65 countries received these substandard prothesis. As a consequence of this event, the National Agency of Medicine and Health Product Safety (ANSM) in France was created. Furthermore, at a European level, the European Commission embarked on a full regulatory restoration of the medical device regulations with the intention of providing higher levels of safety for the patients and building back public confidence.

At the top list of medical products or devices that have a higher prevalence of being falsified are surgical equipment such as clip cartridges, surgical mesh, thermometers, plates and screws. Although these devices may seem genuine, their parts may not function properly, which could lead to malfunction and complications. In Taiwan, 13,000 plates and screws were discovered to be fraudulent, affecting a total of 100 hospitals nearby. In 2014, a similar episode presented itself in Los Angeles, as spinal screw implants were discovered to be of poor quality. In addition to these surgical products, intra-aortic pumps are oftentimes a target. Recently $7 million worth intra-aortic pumps had to be withdrawn from the market after defective components were discovered to be fake.

Along these lines, dental products are also remarkably affected by counterfeit. There are numerous low quality and fake dental devices that are made in Asia and sold everywhere else that are posing a serious health threat. From drills to X-Ray machines, braces and air turbines that can be purchased on illegitimate websites with prices well below market value. The braces issue specifically is of great concern as there have been patients affected by very serious infections caused by the lead wiring.

The industry of counterfeit medical products and pharmaceuticals is expected to grow over the next years, which implies that the market will be soon overwhelmed by defective and hazardous medical devices. All such devices pose a health risk to the patients that could ultimately result in injury, permanent disability, or even death.

1.3 Causes of counterfeit in the medical industry

The increase in counterfeit medical products and pharmaceuticals answers to some circumstances that are taking place in our nowadays. One of the most prevailing situations that leads to the increase in falsified products is the demand exceeding the supply. The unfolding of the COVID-19 global pandemic has heightened the vulnerabilities of global trade in pharmaceutical and medical products. The WHO has announced that there has been a considerable growth in the volume of fake medicines linked to coronavirus in emerging countries. Likewise, the Interpol has seized numerous medical products related to the pandemic such as face-masks, hand sanitizers and other personal protective equipment in developed countries. The immense stress behind the

pandemic, along with the product shortages, high-pressure situations, time-sensitive decision making and new supply chains and distribution channels have fueled the emergence of more counterfeit products. In this same fashion, the demand for pharmaceuticals to fight the virus has lead to the commercialization of unauthorized antiviral medications in clandestine websites.

Over the last decade the expansion of E-commerce has yet become a global source of counterfeit medical products and pharmaceuticals. Numerous underground websites sell drugs online at a price below the actual market price. Internet is facilitating these illicit trade activities as it provides counterfeiters a broad consumer base with very limited to no risks. Along these lines, the self-diagnosis and self-prescription tendencies in our society are aggravating the issue, as people tend to consume more drugs online without the need of them being previously prescribed by a doctor. Oftentimes, the consumers themselves do not realize these medicines are counterfeited because of the sophistication of the packaging, posing an even greater risk for their health.

The complexity of the supply chain for pharmaceuticals and medical equipment has been identified as another factor contributing to the counterfeit market. With the pressure behind the manufacturers to ship on time their products, the medical supply chain has become very vulnerable. The risks of having counterfeited products added throughout the supply chain is an ever-present phenomenon that many are trying to resolve with the use of technological tools. Additionally, with the boost of globalization products might be manufactured in a certain country and then packaged in a second country and distributed across borders to be marketed or sold to consumers in a third.

The need to provide medical products to everyone despite of their socio-economic status has forged a ground for substandard and falsified medical goods. Up to two thousand million people around the world lack access to the elemental features of healthcare; from necessary medicines, to vaccines, medical devices and in IVDs tests between others. The constant increase of the prices is leading to a substantial increase of counterfeited medical equipment in developing countries. However, this problem also affects developed countries as they constantly experience the introduction of new, innovative healthcare technologies that drive the industry into better but yet more expensive procedures and products. These high prices are ultimately leading to the falsification of spare parts of the products to make them more affordable. This altogether with poor will and commitment of some governments in certain countries and ineffective regulatory bodies, is giving rise to the escalation of counterfeit medical products and pharmaceuticals.

1.4 Actions taken against counterfeit

There are several approaches to fight counterfeit, from building more solid regulations and making new laws to protecting the goods with novel technologies. With the increase in counterfeit goods there has been a shift in responsibility from governments and regulatory authorities to manufacturers. The role of manufacturers, suppliers and practitioners is unquestionably essential to take measures that assure a competent

approach to detect fraudulent products. After their detection a quick removal from the market is key to protect the end-consumers, for this part help from governmental organization and law enforcement contribution is needed.

Numerous initiatives take place at an international level with the aim to fight counterfeit of illicit pharmaceuticals and medical products. The International Criminal Police Organization (INTERPOL) has coordinated the so called Operation Pangea, that aims to disrupt the online sales of counterfeit medical products from unregulated websites. This operation has worked from 2008 and is still working today seizing a huge amount of fraudulent medical products. In fact, since it started thirteen years ago it has removed more than 105 million units in different pharmaceutical forms and they have made more than 3000 arrests. The coronavirus outbreak has triggered a second epidemic of falsified and substandard products that have flooded the market. From face-masks to substandard hand sanitizers and unauthorized antiviral medications. The value of potentially dangerous pharmaceuticals seized during this operation has amounted up to $14 million. More than 2000 online links were promoting the use of this preventive measures against COVID-19 that did not fulfill the applicable regulations. A total of 34,000 items were confiscated when the pandemic had just begun.[7]

In terms of regulations, at a European level there has been an important restoration often referred as European Medical Devices Regulation (MDR) which includes Regulations (EU) 2017/745 and 2017/746. These regulations serve different purposes, from extending the scope of medical device regulation to also other products such as cosmetic and aesthetic devices to being more strict in the compliance requirements from manufacturers to protect the patients. In addition to this, a national registry has been developed for the manufacturers to register themselves and their devices in a central database that collects all this information, allowing the traceability through a unique device identification (UDI). This system provides a single but yet globalized identification through their distribution and final use. The United States Food and Drug Administration (FDA) and the European Commission between other regulators have joined this initiative with the intention to reach a globally integrated approach to promote patient safety.

The WHO also plays a vital role in combating counterfeit as they act as a body that promotes strong commitment and will from the political member states to tackle the issue from its roots. Their proposal has three key points that are: prevention, detection and response to the threats that these products pose to the end-consumers.

Furthermore, there are legislative measures enforced by numerous international instruments that help fight against counterfeiters. The Council of Europe launched the MEDICRIME Convention which supports countries with a model legal framework to deal with fraudulent medical products. Along these lines, the European Union has a

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[7] *Operation Pangea – shining a light on pharmaceutical crime.* INTERPOL. (n.d.). https://www.interpol.int/News-and-Events/News/2019/Operation-Pangea-shining-a-light-on-pharmaceutical-crime.

Falsified Medicines directive (FMD) that has the intention of improving the security of both the manufacturing and delivery process of medicines across Europe, protecting patients by avoiding the entering of falsified medicines in the supply chain.

1.5 Technologies to fight counterfeit

For years, holograms have been a useful tool to detect fraudulent products and to visually protect authentic goods. Their ease of use and independence on any database, has lead them to be the most used anti-counterfeit technology during the last century. Holograms are a permanent record of the light reflected off an object but in a three-dimensional (3D) fashion, that makes it move as one looks around it. They have evolved significantly during the mid-20th century and albeit, there are highly sophisticated holograms available, the market is still saturated with low-cost holograms that can be effortlessly imitated.

Besides holograms, other frequent solutions implemented to fight counterfeit are luminescent topcoats. As a matter of fact, this technology is widely used in the pharmaceutical industry to ensure the presence of labelling on pharmaceutical products. The patterns formed by these luminescent topcoats are invisible to the naked eye and can exclusively be seen under UV light. Some companies have extended the use of this technology by making it possible for their clients to customize their own patterns in form of a trademark. Thus, enabling them to protect their products from counterfeit down the supply chain.

Likewise, the blockchain technology has promising assets to fight counterfeiting. This technology is nowadays in the public eye by its immense potential to change our day to day life. Its main characteristic is that it provides a decentralized system in which information can be stored. This capacity to collect data can be helpful to have a full traceability of a certain product that is linked cryptographically.

Nowadays is very common to track and trace items by capturing and storing the location of products throughout their supply chain journey. There are several technologies that use barcodes that can be scanned at different locations to ensure their authenticity and to track their way down to the client. These scanners have evolved onto fine-tech electronic sensor tags that can record all the information about a certain item without the need of voluntarily scanning it. One of the most common technologies used for supply chain and inventory management is the Radio Frequency Identification (RFID). This electronic technology allows a remote and wireless authentication of an object that contains a chip with a radio signal. Along these lines, another cutting-edge electronic technology that is being used nowadays is the Near Field Communication (NFC), which is a short-range magnetic induction to facilitate instant data transfers between digital devices when they are held up close. Both technologies, the RFID and the NFC, help provide an excellent tracking and tracing system that helps improve inventory accuracy, enhance asset management and authenticate goods.

In the interest of unraveling the counterfeit issue globally, new biotechnologies are emerging to fight counterfeit. The unique characteristics of biological proteins such as, for instance, DNA, allows for new and more sophisticated anti-counterfeit methods. Implanting a unique DNA code into a product or package allows its full traceability as it contains a unique sequence of genetic information.

Another example of such innovative technologies is the use of systems made up by nanoparticles. Nanotechnology is able to take some of the previously mentioned techniques and enhance their security by making it harder for counterfeiters to plagiarize. Nanoscale data-encryption goes one step further than barcoding, it enables the manufacturer to encode unique nano-structures, nanoparticles and molecular self-assemblies that are completely invisible to the eye. By using nano-patterns, the holograms become more secure, the verification is straightforward and the imitation by criminals becomes very challenging.

1.6 Nanoluxe: a solution to avoid counterfeiting

Nanoluxe is a new company that aims to fight counterfeit of luxury goods by implementing a new cutting-edge nanotechnology. Their research on the subject has lead them to the development of an un-copyable ink-based tracking nano-platform. The particles that constitute the ink give a unique signal that can be rapidly (≤2 seconds) measured with a handheld optical reader.

The nanoparticles that form the ink created by Nanoluxe can be inserted in several types of surfaces, allowing a wide range of possible products. When the particles are inserted into a metal surface, Polydimethylsiloxane (PDMS) or cellulose adhesive are used to stick them together. Once they are placed with a laser in the surface of the good, they are read with the SERS technology. On the other hand, for porous surfaces such as leather, skin or cellulose, it is not necessary to apply the adhesive as the particles are able to penetrate in the tissue without further help. Furthermore, the ink adheres in any kind of physical material such as leather, cotton, metals or plastics, for at least 10 years and without affecting the appearance of the good.

a) The technology behind Nanoluxe

The association of nanoparticles can form numerous and unlimited patterns, giving rise to a totally unique and unrepeatable signal that can be read in situ and in multiple scenarios along the supply chain. In order to verify the authenticity of the good, the nanoparticles pattern has to be read. For this purpose the SERS technology is used. In normal Raman spectroscopy, a laser source, normally a monochromatic light, hits directly on a certain sample that absorbs this light. However, a small part of the light is scattered in all the directions in an inelastic manner.

Due to the lack of sensitivity, Nanoluxe uses the SERS technology in order to enhance the signal provided by the normal Raman. The SERS method enhances the image 6-8 orders of magnitude, this same signal read with the classical Raman spectroscopy

cannot be measured as it has a very low concentration. Its functioning is based on the amplification of electromagnetic fields that are generated by the excitation of localized surface plasmons. The plasmonic effect occurs when there is an interaction between free electrons in metal nanoparticles and an incident light. These particles have an electron density that can conjugate with electromagnetic radiation of wavelengths that are a lot larger than the particle itself due to the dielectric-metal interface that lays between the medium and the particles.

Plasmonic metal nanoparticles -that can be made up of gold, silver or platinum- have a high efficiency of absorption and scattering of the light. Nanoluxe has developed gold SERS nanoparticles that besides having this high efficiency, they have other advantages that make them applicable to different and varied fields. Gold has remarkable properties in the nanoscale as it has very high resistance to oxidation and other properties that are not seen at the macroscale. For instance, there is an optical effect at the nanoscale that shows in gold that is completely different than other ordinary nano-particles. These structures absorb in the near infra-red instead of the visible, and this characteristic is currently being under study for medical applications such as tumor eradication. Hence, they have an adjustable morphology, by simple modifications you can change the shape and each specific shape has particular optical properties. Furthermore, they are nontoxic and biocompatible, a characteristic that allows its application in the medical industry.[8]

2. METHODS

Nanoluxe has developed a technology that can revolutionize the anti-counterfeit market, but besides their focus on luxury goods the technology developed allows them to also have a potential to enter into the medical products anti-counterfeit industry. However, a thorough analysis of the market and competitors must be endured in order to assess the viability of throwing this technology to this market.

2.1 The business model and key players

The first step to carry out a market analysis is to have previously defined the business model you plan to have and the targeted services or products you are willing to sell. This market analysis will explore the possibility for Nanoluxe of expanding the scope of their business into the medical industry and within this industry in which specific niche its implementation can be more successful.

a) Medical products and pharmaceuticals supply chain analysis

The development of either a new drug or a medical device always starts with a Research and Development (R&D) process in which a prototype of the good is designed, the regulatory approval is managed and the engineering process take place. Afterwards, the process that comes next is the components manufacturing. Most of the times the

[8] Cortie, M. (2007). The Weird World of Nanoscale Gold.

manufacturers themselves do not create all the components that made up the product. Hence, for each constituent of the product there are several input suppliers that can provide resins, metals, chemicals, textiles, etc. From these input suppliers there is parallel development of each of the constituents of the medical device. Some of these may be the software development process, the building of electronic and electrical components, the work with precision metals, the molding and extrusion of plastics and the weaving or knitting of textiles. Once all the constituents are created there is the assembly of the parts, the packaging and the sterilization. This process is executed by the manufacturer responsible of the medical device.

In the case of the pharmaceuticals, they as well need a huge amount of different materials that are brought up by suppliers, some of them are substances or chemicals and gases. Once these materials arrive, the active pharmaceutical ingredients (APIs) are developed. There are companies that manufacture the APIs and others that buy them to other pharmaceutical firms. The manufacturing of API consists in different chemical reactions in large containers called reactors. Inside these reactors the reactants are mixed and heated, this mix is then cool down and it crystallizes into a powder that is later formulated. During the formulation process the API is mixed with solvents, binding agents and pharmaceutical excipients and then they are dried until they form little grains of very few millimeters. Then they are brought up to the table compression machine in which they are shaped into pills. The tablets are then slightly modified to make it pleasant for the patient and easy to consume. During all these steps there are highly strict regulations and they carry out control sampling of all materials and tablets are weighted measured and checked in many and diverse parameters such as shape, color, dissolving qualities, etc. Finally, the drugs are packed, which is a highly automated system.

Once the manufacturing process has been accomplished the process of distribution takes place. The buyers can be different types of profiles from wholesale distributors, individual patients, public and private hospitals and even individual patients. Wholesale distributors are individuals and companies that buy products in bulk amounts directly from the manufacturers in order to later redistribute these goods, oftentimes to retailers. This type of profiles play a major role in life sciences as they pretend to make the supply chain management more efficient. When there are wholesalers the manufacturers sell bulk quantities of medications or medical devices to a comparatively small number of wholesaler repositories instead of shipping to a huge amount of pharmacies, hospitals, and outpatient dispensing outlets. In addition to this, wholesalers are able to work as a mediator in negotiations between smaller hospitals, and pharmacies, between others, and the actual manufacturers.

The marketing and sales process classifies the products in subcategories in order to sell them to the buyer. The distributors use the help of the marketing and sales process to get the final product to the clients. A salesperson is normally in charge of selling and distributing specific medical devices such as orthopedics, ventilators, monitoring devices, cardiovascular implants and pharmaceuticals, between others. Their role is to have a profound knowledge in the market and know the key stakeholders in each

specific medical field. In addition to this, the salesperson collaborates actively in the final process of the supply chain which is the post-sales services.[9]

b) Targeted services and key players

Once the supply chain process has been identified for both pharmaceuticals and medical devices, the Nanoluxe technology has to be placed specifically in a certain place along the supply chain according to this information. The key players are the manufacturers, distributors and the hospitals or healthcare facilities, as they are the final recipients of the medical product. Because of the cost and risk associated with the influx of counterfeit products, companies are starting to develop strategies to deal with this issue by tightening supply chain control and management techniques and protecting their brands with emerging technologies that help in detecting fraudulent products. Hence, manufacturers are certainly the main client for Nanoluxe.

The services that Nanoluxe sells are, on one hand, the placing of the ink into the material and the equipping of the technology with the optical reader. The optical reader is the tool that allows the traceability as it shows the information of the product and allows its authenticity down the supply chain. This appliance has to be given to other participants of the supply chain in order for them to check the authenticity of the good.

Counterfeit goods have several ways of entering into the market, but the real mapping of these routes is a quite arduous task to undertake. According to the OECD in their report titled *"Mapping the real routes of trade in fake goods"*, they state that counterfeit products can be brought into the market with relative impunity. One of the ways of entering these products is with the illegal relabelling of the item with a protected trademark. Another way is to break down cargoes into a sett of smaller shipments as it lowers the possible mistrust and if they are intercepted there is a lower risk of the trademark holder to take action. Furthermore, counterfeit products can also be reshipped in containers with a large amount of legitimate items.

With globalization, products might be manufactured in a certain country and then packaged in a second country and distributed across borders to be marketed or sold to consumers in a third. For this reason is important that the distributor reads the ink that has been placed by the manufacturer to prove that all packages contain genuine items. In addition to this, there is currently a tendency for distributors to play a more important role and provide a wider range of specialized services such as product repackaging. In this repackaging the medical products could be tampered, and genuine parts of a product can be exchanged by cheaper ones. If the fraudulent product is detected by the distributor, then these can be extracted from the market before reaching the hospital or healthcare facility. In this way, it is easier to detect where this falsification occurred and identify the counterfeiters. On top of this, for logistic purposes it is easier for the

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[9] *How Does the Pharmaceutical Supply Chain Work?* Datex Corporation. (2021, May 18). https://www.datexcorp.com/how-does-the-pharmaceutical-supply-chain-work/.

manufacturer to still provide to the hospital the materials that they need, despite the amount of falsified products being counted before as genuine items.

At the end of the supply chain, the hospital or healthcare facility would have to check again and trace the origin of the medical product to reassure that they are the originals. Depending on the product, the checking could be effected at different places of the hospital. If the item falls into the category of medical equipment and pharmaceuticals, then the Purchasing and Supplies department of the hospital could check and trace the products that come in bigger packages. This department is in charge of hospital logistics that include the purchases, reception of goods, stock management, information system management and telemedicine between others. Nonetheless, if the product is bigger such an X-rays machine or quite expensive such as implants, they can be checked with the optical reader in their final hospital sites. In the case of the implant, the surgical technologist that is in charge of making sure all the surgical instruments are well prepared for surgery, could read with the optical reader the information about the implant in the pre-operating room. In the case of the X-rays machine, the technician that signs the implementation of the machine, could check with the optical reader to make sure everything is in order.

2.2 Market analysis

The main purpose of the market analysis is to determine the viability of the Nanoluxe technology in the medical products market as an anti-counterfeit measure. In addition to this, the goal is to determine the market niche for Nanoluxe within the medical industry.

a) Industry outlook and market size

The medical devices market is made up by medical equipment or devices that participate in the diagnosis, treatment and monitoring of medical conditions. This industry includes establishments that manufacture these devices that are applied in many varied fields such as in-vitro diagnostic devices, diagnostic imaging equipment, dental equipment and supplies, ophthalmic devices, cardiovascular devices and hospital supplies between others.

The global medical devices market is expected to grow in the following years although there are certain restricting factors limiting the growth of the market that will be analyzed. The market worth of the global medical devices market was of $456.9 billion in 2019 and its Compound Annual Growth Rate (CAGR) was of 4.4% from 2015 to 2019. However, from 2019 to 2020 there was a decline in the market worth and CAGR that was later improved with the boost in consumption of ventilators and other respiratory devices used during the COVID-19 pandemic. For the next years, the market is expected to grow and reach a CAGR of 6.1% and reach a $603.5 billion by 2023.

Advancements in health technologies, an aging population and a higher prevalence of chronic diseases are some of the factors that are encouraging this market growth. Still, there are some market restrainers that have hindered the market before and that might

be a burden for the prosperity of the market. Factors that could interfere in the medical devices industry include supply chain disruptions that flourish after the COVID-19 pandemic, higher economic costs due to an increase in interest rates and more demanding regulatory procedures.

On the other hand, the market drivers for a higher consumption of medical devices are, as mentioned before, the aging in population and increase in prevalence of chronic diseases. This demographic shift implies that people nowadays do not die due to acute illnesses such as infections and they survive being more prone to suffer a chronic disease. The United Nations states that the proportion of total deaths globally due to chronic disease are predicted to experience a growth to 70%. These chronic diseases also debilitate their patients making infections such as COVID-19 very complicated to cure as they affect organs such as the lungs. Not enough physical activity, bad nutrition and damaging habits such as drinking alcohol or smoking, cause a high number of these diseases. At a global level, the number of people living with diabetes has increased considerably from 108 million in 1980 to 422 million in 2014. Currently this data is rising even more rapidly in low- to middle-income countries. Vascular diseases are the most common cause of death globally as 17.9 million people die every year from cardiovascular diseases, representing 31% of all deaths globally, and over three-quarters of these deaths occur in low- to middle-income countries. In high-income countries, approximately 50% of citizens suffer from chronic disease while the other half are diagnosed with cancer during their lifetime.

Another market driver that is tightly related with the increase in prevalence of chronic diseases is the higher focus on novel technologies, as well as the growing adoption of home care devices. The emergence of global markets that are starting to consume more medical devices due to their improvement in economic prosperity and a growing medical awareness is leading the medical industry to innovate. Global health expenditure increases as the need to provide to every country despite its economical situation.

The pharmaceutical manufacturing market size is also expected to reach $1,175 billion by 2030 and it is also expected to grow. The innovations in oncology, autoimmune and diabetes treatments are fueling the international pharmaceutical market. The focus in both treatments and prevention of these diseases is a clear advantage for this industry. Self-medication and self-diagnosis consumer behaviors are increasing the over the counter medications (OTC) that are those medications that do not need to be prescribed by a doctor.[10]

In terms of the anti-counterfeiting market, the data about the worth of the anti-counterfeit packaging market alone was $4.90 billion in 2019 and expected to grow to $17.47 billion by 2027 with a 17.25% CAGR. The rising consumer awareness

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[10] *What are the drivers of market growth in the pharmaceutical industry?* Wonder. (2017, July 5). https://askwonder.com/research/drivers-market-growth-pharmaceutical-industry-2fgnkjk7c.

pertaining to the harmful effects of fraudulent goods and the increased concern to protect brand identity are the two main factors that promote this gigantic market growth.

One of the restraints that apply to the medical devices, pharmaceutical and anti-counterfeit markets is the data security issue. The foreseen increase in the remote patient monitoring devices will increase the cybersecurity risks, including the patient data theft. Anti-counterfeiting measures increase the traceability by making the supply chain more transparent but there is always private data that can contain sensitive information about health conditions that can be stolen for illegitimate purposes.

b) Market need

Healthcare brand owners are particularly aware of counterfeiting as it has very negative effects in terms of revenues. Notwithstanding, the main issue with the increase of spurious products is the loss of brand integrity as well as the damage to the brand owner's reputation. In addition to this, manufacturers find themselves losing considerable amounts of money for protection, investigation and litigation expenses related with counterfeited products.

For these reasons, there is an urgent need to develop strategies to deal with this issue. Apart from the reinforcements of regulatory pathways and laws, there has been a significant shift in responsibility to the manufacturers. Manufacturers instead of reacting to these counterfeit scandals and incurring the resulting liabilities, they want to take a proactive stand and protect their brands with technological solutions. These solutions will enable them to have a reliable system to track their products down the supply chain. All in all, their main focus is on tightening the supply chain control and management in order to have full traceability of the products and preventing the entry of fakes, forgeries, copies or counterfeits.[11]

c) Market segmentation

The segmentation of the market will be based in three different categories. The first one is the type of medical product targeted, then it will be classified by end user and finally by geographical location.[12] Likewise, the market will be segmented into medical devices on the one hand, and in pharmaceuticals on the other hand. Firstly, the medical devices market will be analyzed. The WHO estimated that there are about 2 million different kinds of medical devices all over the world, categorized into more than 7000

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[11] Sanchez, F., & Petrie, J. (2013). COUNTERFEITING: Are your devices at risk? *Medical Plastics News*.

[12] *European Medical Devices Market*. Market Research Firm. (2020, May). https://www.marketsandmarkets.com/Market-Reports/european-medical-devices-market-241277169.html.

generic devices groups.[13] For the purpose of this market segmentation, the most profitable types of devices will be assessed, being those thirteen different groups.

Type of medical device	Market value	Growth rate (CAGR)
Orthopedic devices	USD 53.44 billion	6,6 %
Cardiovascular devices	USD 42.4 billion	6,9 %
Coronary stenting	USD 7.7 billion	4,7 %
Peripheral stenting	USD 9.2 billion	6,5 %
Diagnostic imaging	USD 20.1 billion	5,2 %
IVD	USD 74.1 billion	6,7 %
MIS	USD 24 billion	9,85 %
Wound management	USD 2.19 billion	4,6 %
Diabetes Care	USD 9.2 billion	5,8 %
Ophthalmic devices	USD 53.4 billion	4,2 %
Dental devices	USD 5.4 billion	12,1 %
Nephrology	USD 12 billion	4 %
Respiratory care devices	USD 58.1 billion	261,1 %

Table 1: Market segmentation based on type of medical device.

The In-Vitro diagnostics (IVD) is the strongest segment (see Table 2), it consists in all the tests that can detect disease, conditions and infections, and they can be carried out in laboratories, healthcare facilities or even at home. Only IVDs constitute the 13% of the entire global medical devices market. Some products that fall into this category are blood sugar monitoring systems for diabetics, urine test strips, pregnancy tests or hepatitis and HIV tests.[14] The following segment that has a bigger size is the orthopedic devices market. These devices can be sub-classified into internal and external fixation devices. In terms of internal fixation devices there are screws, plates, wires and pins, intramedullary rods and nails, and spinal fixation devices. The external fixation devices are fracture fixation including the radius, tibia and pelvis, and the bone lengthening devices.[15]

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[13] World Health Organization. (n.d.). *Medical devices.* World Health Organization. https://www.who.int/health-topics/medical-devices#tab=tab_1.

[14] World Health Organization. (n.d.). *In vitro diagnostics - Global*. World Health Organization. https://www.who.int/health-topics/in-vitro-diagnostics#tab=tab_2.

[15] *Orthopedic Hardware*. UW Radiology. (2017, April 18). https://rad.washington.edu/about-us/academic-sections/musculoskeletal-radiology/teaching-materials/online-musculoskeletal-radiology-book/orthopedic-hardware/.

Other strong segments are the cardiovascular devices and the ophthalmic devices. The cardiovascular devices that are implantable include electronic deices such as pacemakers, implantable cardioverter defibrillator (ICD), biventricular pacemakers and cardiac loop recorders. The main function of these devices is to help control and monitor de irregular heartbeats in patients with certain disorders and heart failure. Additionally, stenting devices have a very high market share due to the increase of chronic diseases such as atherosclerosis that diminish the lumen of the blood vessels. [16] Ophthalmic devices are designed for diagnosis, surgery, and vision correction. With the increase in prevalence ophthalmic related diseases such as glaucoma, cataract and other vision-related issues, the ophthalmic devices market size is notably significant, even higher than the cardiovascular devices market.[17]

Respiratory aid devices were decreasing in terms of market size and CAGR at about a -12% level, but the boost of the COVID-19 pandemic has more than doubled the market. Many big companies such as Phillips have developed ventilators with several applications such as high flow, invasive and non-invasive ventilations for COVID-19 patients in the Intensive Care Unit (ICU). The outbreak of infectious diseases affecting the respiratory system because of COVID-19 has made this market grow at a gigantic rate. However, once the epidemic is over, the demand for this products will decrease considerably as hospitals will already be provided with such equipment.[18]

The Minimally Invasive Surgery (MIS) devices are also a leading market thanks to the advantages that they provide in comparison with regular surgeries, such as for instance the decrease in infections caused by the intervention.[19] The dental market, that was one of the most affected by counterfeit is increasing at a very high rate. The growing prevalence of dental infections and other periodontal diseases are the major factors propelling the growth of this market.[20] The diagnostic imaging market is also increasing because of the incremental innovations and advancements in medical imaging

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[16] *Types of Cardiac Devices*. Patient Care at NYU Langone Health. (n.d.). https://nyulangone.org/conditions/cardiac-device-management-in-adults/types.

[17] Telugunta, R., Sumant, O., & Urde, K. (2020, November). *Ophthalmic Devices Market Size: Industry Analysis, (2020-2027)*. Allied Market Research. https://www.alliedmarketresearch.com/ophthalmic-devices-market.

[18] *Respiratory Care Devices Market*. Market Research Firm. (2020, June). https://www.marketsandmarkets.com/Market-Reports/respiratory-care-368.html.

[19] *Minimally Invasive Surgical Instruments Market*. Market Research Firm. (2020, March). https://www.marketsandmarkets.com/Market-Reports/minimally-invasive-surgical-instruments-devices-market-682.html.

[20] *Dental Equipment Market: Industry Size 2021 to 2026 - Mordor Intelligence*. Dental Equipment Market | Industry Size 2021 to 2026 - Mordor Intelligence. (n.d.). https://www.mordorintelligence.com/industry-reports/global-dental-equipment-market-industry.

technologies such as Artificial Intelligence (AI) and the rise in healthcare expenditure.[21] Lastly, the diabetes care related market is also significantly large, taking into consideration that it only includes one disorder. These devices include blood sugar monitoring systems between others, that are also included in the IVDs market.

System of the body affected	Type of drugs
Digestive system	Antacids, antiflatulents, proton pump inhibitors, laxatives, and antispasmodics.
Cardiovascular system	Beta-blockers, diuretics, antiarrhythmics, vasoconstrictors and vasodilators, anticoagulants and haemostatic drugs.
Nervous system	Psychedelics, hypnotics, anaesthetics, antipsychotics, antidepressants, antiepileptics, barbiturates, antihistamines.
Immune system	Antibiotics, Antiviral, Anti-fungal, Anti-inflammatory, Anti-allergy
Endocrine system	Androgens, estrogens, gonadotropin, corticosteroids, thyroid hormones

Table 2: Classification of types of drugs

The pharmaceutical industry is often segmented by classifying the types of drugs by the effects they have in a certain region of the human body. Thus, they can be classified as shown in Table 3. In addition to this, the most common drug groups are: oral drugs, parenteral formulations, topical medicines, modified release formulations, novel drug foundations and oncological formulations. [22]

The medical products users are heterogeneous and made up by very varied classes, groups and types. End-users are defined as *"a person who uses a medical device for treatment and/or care of him-/her−self or someone else and that is the ultimate beneficiary of the usage of a medical device"*. Hence, the patient him-/her-self can be the end-user or both the user and end-user. For instance, a surgeon that is about to perform a surgery to a patient is the user of the implant that will be put in his patient and thus, his patient will be the end-user of that medical device. However, if the patient has diabetes and he or she has to use a blood sugar monitoring device, he or she will undertake the role of both the user and end-user. Accordingly, medical devices users

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[21] Ugalmugle, S., & Swain, R. (2020, August). *Medical Imaging Market Statistics: Global Trends Report 2026*. Global Market Insights, Inc. https://www.gminsights.com/industry-analysis/medical-imaging-market?gclid=Cj0KCQjwzYGGBhCTARIsAHdMTQyf9IBxlqE0WnRBmzFwoRR6SqzA7Xy4OGaCSYCIniGB49Ylu7XqDFIaAq6-EALw_wcB.

[22] Athulya. (2021, February 2). *How Many Types of Pharmaceutical Companies Exist?* Vakilsearch. https://vakilsearch.com/advice/how-many-types-of-pharmaceutical-companies-exist/.

might include trained, semi-trained and even untrained individuals, as some medical devices can be used without medical supervision.

Lastly, the market segmentation by geography will be performed by first dividing the global market into five different and smaller regions. These regions have different market size and market value, depending on their technological advancements and economical situation. The following table shows by region the value of each market both in terms of pharmaceuticals and medical devices:

World region	**Pharmaceutical market value**	**Medical devices market value**
North America (USA & Canada)	USD 416.8 billion	USD 185 billion
Europe (UK, Germany, France, Italy, Spain, Scandinavia and rest of Europe)	USD 219.9 billion	USD 120 billion
Asia Pacific	USD 277 billion	USD 88 billion
Latin America	USD 70 billion	USD 29 billion
Middle East & Africa	USD 25.6 billion	USD 63 billion

Table 3: Market value by geographical regions

d) Competition

The competitive analysis assesses the strengths and weaknesses of the current potential competitors, to provide both an offensive and defensive strategic context to identify opportunities and threats. The first step of this competitive analysis is to determine which are the most profitable and established type of anti-counterfeit methods. In this case, for simplicity purposes the most recurrent method for brand protection is to place a technology in the package of a certain good to later authenticate it. The anti-counterfeiting packaging market alone is worth $17.47 billion and it is expected to grow at a 17.25% CAGR by 2027. Hence, it is a quite consolidated market as it is dominated by approximately ten major players, some of them are going to be depicted in Table X. Over the last few years, a considerable escalation of consumer awareness about unapproved reproductions of products or substandard goods has given rise to numerous industries being forced to adopt anti-counterfeiting packaging measures. The following table includes the most successful and long-established companies that implement anti-counterfeit technologies.

Name of the company	Technology	Year	Country
Cypheme	**Artificial intelligence (AI)** solution that detects counterfeit products by analyzing the product's packaging with a neural network, using only a cellphone camera.	2015	France
Zebra Technologies	Electronic tags that enable the tracking and identification of products, processes and people. **Real Time Location System** (RTLS) and **RFID.**	1969	USA
Applied DNA Sciences Inc	**Polymerase chain reaction (PCR)** based manufacturing system that makes large quantities of linear DNA for various markets and purposes such as supply chain security and brand protection.	Unknown	USA
Avery Dennison	Packaging materials company that uses customized **luminescent topcoats** to track and authenticate products.	1935	USA
TruTag Technologies	Tag, track and trace of drugs and and other life-critical consumables with **invisible** and **edible barcodes.**	2011	USA
Bilcare	Innovation-led packaging solutions that protect brands by ensuring the delivery of genuine medicines to patients with a wide range of specialty **Polymer Films** and **Aluminum Foils**.	1987	India
AlpVision	**Invisible** anti-counterfeit and product authentication solutions based on **machine learning** that can be **read with a phone**. It can be both applied to the packaging and to the product itself.	2001	Switzerland
Sicpa	**Visible security solution** characterized by vibrant colors and engaging **visible effects** that are quick and easy for end-users to authenticate.	1927	Switzerland
Authentix	Wide range of solutions such as **optically-variable inks** technologies (**tamper-evident closures and labels**) security technologies (**holographic seals and labels**)	1994	USA
Curacode	Company that applies **cutting edge laser technology to print high-security, low cost authentication labels** that secure supply chains.	2021	UK

Novalia	**Printing electronics** to secure the packaging and provide traceability.	2006	UK
Alien Technology	World leader in **RFID technology** using chips, tags and readers for item tagging, retail/apparel, transportation, life sciences and many other applications.	1994	USA
Arylla	This company uses a proprietary **ink** to print invisible identifiers or **nano-tags** on every product. **Any smartphone can connect to these tags** without downloading any new apps.	2015	Canada
VerifiR, Inc.	Anti-counterfeit and customer engagement platform for consumer product manufacturers. The solution is built upon combining **near-field communication (NFC)** technology that exists on consumers' mobile phones with **cloud analytics.**	2015	USA
SmartChip Microelectronics	**RFID chips and systems** that provide authentication solutions to manufacturers.	1995	Taiwan

Table 4: Competitor analysis

As it can be seen in Table 4, most of the long-established companies depicted started their business in the packaging methods for different types of products and then they have used their brand image to promote the protection of goods with anti-counterfeit technologies. The newer additions to the anti-counterfeit market are applying more modern approaches based in the advancements of biotechnology and some Artificial Intelligence (AI) approaches.

Notwithstanding, the technology more widely used and with a higher prevalence in the table of top ranked anti-counterfeit industries is the RFID. RFID-tags are becoming the most used tools to identify products, as they automatically determine the origin of a product through low-power radio waves. Governments are openly promoting and even obligating their use in order to track and trace products down the supply chain, which is a fact that is driving its market growth. Based on the technologies used in the previous classification of the competitors, now a price approximation for each technology will be calculated, along with the main advantages. At the end of the table, Nanoluxe will be added for a further comparison later on.

From this table that contains the prices for each technology (Table 5) and their advantages, the SWOT analysis has been carried out in the following table. In terms of strengths, the internal factors that give Nanoluxe an advantage have been identified. On the other hand, for the weaknesses, the internal factors that work to Nanoluxe's disadvantage have also been determined. For the purpose of stating the possible opportunities, the external factors that pose opportunities have been pinpointed. Lastly, those external factors that pose a feasible threat have also been included.

TECHNOLOGY	PRICE	ADVANTAGES
RFID	**Handheld RFID reader** can cost anywhere between **$1250** to **$20,000** each, depending on the level of automation offered. The tags are **$25** or up depending on the **battery life.** They can reach up to **$100** or more. But their **production** is quite cheap around **$0,05-$0,10.**	• **Do not require line-of-site** as normal barcoding systems. • **Multiple RFID tags** can be detected and **read remotely** and **simultaneously.**
NFC	Average of **$0,25/chip.**	• Facilitation of **direct and seamless communication channels** with customers.
AI	No material is needed but the price depends on the **level of development and the number of AI-tasks.** It can vary from **$6000-$300,000.**	• It can be applied in **websites** that sell pharmaceuticals to ask as a seal of quality. These algorithms and neural networks can track the origin of the product.
DNA Sciences - Signature DNA	**$20-$30 for items** valued **under $200** but can increase depending on the item.	• Works as a **lock and key model** where the DNA in the package or material can only be unlocked with its compliment DNA pattern.
Luminescent topcoats	Approximately **100 kg** of ink cost **$20,** the UV detectors that have a wide range of prices, from **$900 to $7000.**	• **Customizable** with the trademark of the customer and difficult to imitate by counterfeiters • It can be **authenticated by multiple parties** (brand owners, consumers, etc) in the supply chain.
Nanoluxe	**Optical reader** oscillates between **$11,000 and $19,000** and i**nk $0,25/ tag.**	• **Biocompatible ink** that can be placed both in the packaging and in the product. • **Lasts for more than 10 years** without modification. • It can be **applied to different surfaces.** • **Hard to imitate** and **easy to use.**

Table 5: Price and advantages of different anti-counterfeit technologies.

S - STRENGTHS: • The ink can be placed in the product itself or in the packaging. • The ink is cheap and many items can be tagged at a relatively low price. • The ink lasts more than 10 years and they do not have battery life. • The patterns created are very hard to imitate by counterfeiters.	***W - WEAKNESSES*** • The optical reader is expensive, the competition can read their tags with a smartphone. • The optical reader can only read one product/tag each time. It cannot recognize multiple products all at once.
O - OPPORTUNITIES • Possibility to apply this technology directly on implantable medical devices as it is biocompatible. • Growth of brand awareness towards anti-counterfeit measures. • Increase of counterfeited medical products due to the COVID-19 pandemic.	***T - THREATS*** • Data protection problems. • Need for a standardized platform that collects all this data. RFID technology being established as the main authenticity method.

Table 6: SWOT analysis

In conclusion, Nanoluxe can focus both in the tagging of the package and that of the product itself, which clearly gives a competitive advantage that only the AlpVision company depicted in Table 4 has.

e) Potential customers and target market

The potential customers of Nanoluxe are manufacturers of both medical devices and equipment, and pharmaceutical companies, that are in need of a trustworthy technology that allows the traceability and authentication of the goods in different touch-points during the supply chain. Based on the needs, the consumers are going to be those companies that are worried about brand-image protection and that care about the wellbeing of their consumers. Geographically, they can be at any part of the world. However, due to the varied regulatory frameworks it is preferably that they concentrate first in the European territory. In terms of firmographics, which evaluate the size of the company and the products made, in the case of the medical devices, the target market will be separated into three different categories:

- **Implantable medical devices:** These types of devices go inside the human body. These companies must be targeted because Nanoluxe offers the possibility of having tagged implantable devices that go inside the human body.
- **Medical equipment and IVDs:** This includes surgical equipment companies and IVDs manufacturers that manufacture highly used devices such as blood sugar monitoring systems for diabetics.
- **Medical imaging devices:** The high incidence of X-rays machines being counterfeited along with their high price, make them a good candidate to be targeted and protected by Nanoluxe.

In terms of pharmaceuticals, there are different kinds of pharmaceutical companies that manufacture different types of drugs and that have different approaches. The following table shows the most common ones:

Industry	**Description**
Mainline pharmaceutical companies	Largest drug companies that have developed several drugs. They are well-established companies with a wide range of products and they both manufacture and invest in R&D. **Examples**: Pfizer, Merck & Co.
Research and Development Companies	Smaller, research-oriented companies that focus on R&D activities. They do not have drugs in the market but they assist bigger companies with clinical trial observation a subcontractors on larger scale projects. **Examples**: Bristol Myers Squibb
Generic pharmaceutical companies	Generic drug companies help mass-produce drugs and they do not invest in R&D. They bring patent-expired medicines to the market at lower costs. **Examples:** Mylan Pharmaceutical Company, Teva Pharmaceuticals
AI Manufacturers	These organizations produce bulk compounds and biomolecules between others to help create vaccines, serums, and other products. **Examples:** Jansen, Sanofi, Novartis.

Table 7: Types of pharmaceutical companies

The generic pharmaceuticals companies are a good focus for Nanoluxe as they produce a big amount of drugs and most of them are general drugs. The most counterfeited drugs were those that were more common amongst the population such as for instance antibiotics. These drugs are highly counterfeited in developing countries as often the demand exceeds the supply.

f) Barriers to entry

The barriers to entry to the market are on the one hand, the hard regulations that will be involved for allowing the ink to go into the product itself. As it will be highly in contact with the human body and nano-materials regulations are quite hard and expensive to process. Along these lines, another barrier is the level of consolidation of the market. The anti-counterfeit market has several strong competitors that have been around for a long time and that have a long-established reputation. Being brand-protection and anti-counterfeit technologies such a delicate issue for companies, it is hard to entry to the market and make your product and brand trustworthy.

2.3 Pricing policy and strategy

The pricing policy will be carried out taking into consideration several aspects such as the production costs, the value of the technology, the demand for such technology and the competition. The pricing strategy will tackle the approaches that will be taken as a reaction to market conditions, such as the price set by the competitors.

a) Supply and demand analysis

One of the first things to consider is the demand for anti-counterfeit technologies. As it has been stated several times, the demand for anti-counterfeit technologies is presumed to increase over the near future due to the rigorous laws and regulations imposed by governments. In addition to this, the growing demand for medical products within the pharmaceutical and healthcare sector are indications that this tendency will last over the next few years. The elasticity of the demand is another factor that must be assessed, this concept measures how sensitive the demand for a good is compared to changes in other economic factors. A change in the price of a luxury car can cause a change in the quantity demanded. However, a change in the price of a toothbrush will not affect so much the quantity demanded as this product is much more needed and necessary for people than a luxury car. Hence, the medical devices and pharmaceutical industries are characterized by an inelastic demand. Changes in price do not affect as much the consumption of certain products as they are necessary to survive. This is an advantage as opposed to the luxury goods market for Nanoluxe.

The supply of anti-counterfeit services is quite extensive and the market is pretty consolidated as there are around fifteen long-established companies. As it was shown in Table X, there are an extensive amount of technologies available and different companies that sell diverse methods to fight counterfeit. Thus, although the demand is pretty high the supply is large as well. In terms of pricing, the competitors have quite

similar prices, but they depend a lot in the type of technology that they are using. More reliable technologies are often more expensive whereas less sophisticated technologies have more competitive prices.

b) Nanoluxe production costs

Nanoluxe presents production costs of 200€ per every 200ml of ink, at a lab level. However, if this ink is produced at an industrial level the prices might diminish significantly. Nonetheless, for each tag it is only needed 20µl of ink, so the initial cost for the ink necessary to tag one item is 0,20€.

c) Price segmentation by targeted consumers

In addition to this, it is important to take into consideration that in order to place the ink to an implantable device or a product that might touch inside a patient's body, the regulations are going to be quite arduous, long and expensive. For this reason, the pricing policy will be flexible. A flexible pricing policy means that Nanoluxe will offer the same product to customers at different and negotiable prices. In order to do so, a segmentation into the different categories will be implemented to apply different prices to each, based on several factors that will be examined now.

- Implantable medical devices
- Medical equipment and IVDs
- Medical imaging devices
- Packaging of pharmaceuticals and medical products

Different prices will be applied for the same product following what it is referred as **discriminatory pricing policy.** These variations in price are due to the specific characteristic of the targeted market. This strategy is based in the differences in the elasticity of the demand and other economical terms. The reasons behind this price segmentation is due to the fact that the consequences of having one medical device or another falsified makes an enormous difference. For instance, falsified IVD tests such as blood sugar monitoring systems can endanger the life of a person in only one use. Other devices or pharmaceuticals that are not as crucial for the survival of the patient, such as for example, a thermometer, although they are potentially dangerous, the life of the patient is not in immediate risk.

Implantable medical devices are more expensive per se than other medical equipment. If a falsification of an implantable medical device occurs, the consequences can be fatal, both in terms of health risk for the patient and in economic terms for the company. To illustrate this, the the PIP breast implants scandal is a good example. As surgeons began to complain about the high rupture rates of the implants, the amount of legal complaints directed to the company was unbearable and this resulted in the company's bankruptcy, even before the medical safety agency recalled the implants. Hence, apart from the health impact, the economic and brand-image repercussion are also another factor to take into consideration when selecting the price. Nanoluxe's clients will pay for both,

ensuring a good brand-image and reputation and taking care of the health risks that counterfeit products pose to their patients.

d) Price policy and strategy

Nanoluxe will charge the consumers based on three main different aspects that are as follows:

- **The type of signaling model:** Some companies will only need one type of tagging and others will require a special and customized tagging for each item.
- The **number of items to be tagged.**
- **The scanners they need in their facilities to obtain the unique signal and introduce it into the tracking system.**

Additionally, there will be another aspect taken into consideration that is the cost and exclusivity of the product that is being tagged, and what is the effect this product can have in the health of the patient. This indirect price will be charged as a percentage of the total cost of this specific medical device (last column in the tables). Now for each of the categories of medical devices defined earlier a price will be given.

CASE 1: IMPLANTABLE MEDICAL DEVICE

	Units tagged	**Scanners needed in the facility**	**Licence**	**Reader**	**% of product cost**
One type of tagging for all the products within a company	< 10.000 products/ month: **0,5€/tag** > 10.000 products/ month: **0,2€/tag**	< 10.000 products/ month:**10 scanners** > 10.000 products/ month:**20 scanners**	5.000 €/ year	15 optical readers free based on consumption loyalty of 2 years	5 %
Different patterns of tagging per each product	< 10.000 products/ month: **5€/tag** > 10.000 products/ month: **3€/tag**	< 10.000 products/ month:**10 scanners** > 10.000 products/ month:**20 scanners**	15.000 €/year	10 optical readers free based on consumption loyalty of 2 years.	5 %

Table 8: CASE 1: IMPLANTABLE MEDICAL DEVICE

CASE 2: MEDICAL EQUIPMENT AND IVDs

	Units tagged	**Scanners needed in the facility**	**Licence**	**Reader**	**% of product cost**
One type of tagging for all the products within a company	< 20.000 products/ month: **0,3€/tag** > 20.000 products/ month: **0,1€/tag**	< 20.000 products/ month:**10 scanners** > 20.000 products/ month:**20 scanners**	7.000 €/ year	20 optical readers free based on consumption loyalty of 2 years.	1 %
Different patterns of tagging per each product	< 20.000 products/ month: **0,5€/tag** > 20.000 products/ month: **0,3€/tag**	< 20.000 products/ month:**10 scanners** > 20.000 products/ month:**20 scanners**	18.000 € /year	15 optical readers free based on consumption loyalty of 2 years.	2 %

Table 9: CASE 2: MEDICAL EQUIPMENT AND IVDs

CASE 3: MEDICAL IMAGING DEVICES

	Units tagged	**Scanners needed in the facility**	**Licence**	**Reader**	**% of product cost**
One type of tagging for all the products within a company	< 500 products/ month: **5€/tag** > 500 products/ month: **2€/tag**	< 500 products/ month: **5 scanners** > 500 products/ month:**10 scanners**	5.000 €/ year	20 optical readers free based on consumption loyalty of 2 years.	0,5 %
Different patterns of tagging per each product	< 500 products/ month: **8€/tag** > 500 products/ month: **4€/tag**	< 500 products/ month: **5 scanners** > 500 products/ month:**10 scanners**	12.000 € /year	15 optical readers free based on consumption loyalty of 2 years.	1 %

Table 10: CASE 3: MEDICAL IMAGING DEVICES

CASE 4: PACKAGING OF PHARMACEUTICALS AND MEDICAL PRODUCTS

	Units tagged	Scanners needed in the facility	Licence	Reader	% of product cost
One type of tagging for all the products within a company	< 25.000 products/ month: **0,05€/tag** > 25.000 products/ month: **0,02€/tag**	< 25.000 products/ month: **3 5 scanners** > 25.000 products/ month: **2 5 scanners**	20.000 € /year	20 optical readers free based on consumption loyalty of 2 years.	2 %
Different patterns of tagging per each product	< 25.000 products/ month: **0,1€/tag** > 25.000 products/ month: **0,05€/tag**	< 25.000 products/ month: **3 5 scanners** > 25.000 products/ month: **2 5 scanners**	22.000 € /year	15 optical readers free based on consumption loyalty of 2 years.	2 %

Table 11: CASE 4: PACKAGING OF PHARMACEUTICALS AND MEDICAL PRODUCTS

A pricing strategy has been defined for each one the four medical products categories. The first thing that has been taken into consideration is whether the company needed a single ink pattern for all the products or customized ink patterns for each product. The latter one is always more expensive in the four cases. Additionally, the price for the product units that have been tagged in each of the categories has been defined. The larger the number of tags, the more affordable their price/unit becomes. In terms of the scanners needed in the facility, they have been estimated also based on the amount of products manufactured per month, the larger the number of products the more scanners must be given. The license is payed yearly and depends greatly in the number of products tagged, as the more products you have the more complicated the management and data collection of these products becomes.

A variable number of optical readers will be given in exchange of a consumption loyalty of at least two years. Lastly, the last column represents the variability in price that is caused by the type of medical device. As it was stated earlier implantable devices will suppose a greater investment at the beginning for all the regulatory processes, and they must have a higher price. In order to maintain a logic with the price/tagging, the increase in price will be given by a certain extra percentage that Nanoluxe will gain based in the cost of the product. A breast implant normally costs around 600€, with this approach a 5% of the product price will be added per each product. So in this case 30€ will be added to the tagging price. This increase in price is justified as the protection and reassurance that this product is genuine is very valuable for all the parties involved: manufacturer, surgeon and patient.

2.4 Regulatory requirements

The first step in the regulatory process is to acquire the intellectual property rights (IPR) of the technology. Hence, a patent must be registered at the European Patent Office (EPO) to get the European protection and exclusivity of the rights over the Nanoluxe technology for a period of 20 years. Before the patent submission the technology must have been validated previously in the laboratory. The patent approval process can take from three to five years, during this period of time, more prototyping demonstrations of the system must be endured.

The second step is to get the International Organization for Standardization (ISO) standards that are required. First and foremost, the ISO 13485 must be considered, this rule is designed to be used by organizations that participate in the design, production, installation and servicing of medical devices and other related medical services. In addition to this, it can also be used by other internal and external parties such as, for instance, certification bodies to help them with the auditing processes.

In Europe, medical devices must contain the so-called Conformité Européene (CE) mark, before being launched to the market. Products that are not included in the Class I category of medical devices must be evaluated beforehand by a notified body that is under supervision of national competent authorities in each country or Member State. This notified body (NB) initiates a certificate in which it is stated whether the product meets the CE requirements. This certificate is later given to the manufacturer that will have to keep as important information regarding the product's safety and CE certification. Apart from this information, the manufacturer has to compile the technical documentation of the product demonstrating compliance with the safety and operational requirements. Albeit the structure of the technical information might vary and it can be quite heterogeneous depending on each manufacturer, there are some parts that always need to appear and these are:

- The product description, what is the expected functionality, the qualitative and quantitative composition and the mechanism of action.
- The label and instructions for use (information provided from the manufacturer to the end user).
- The information about biocompatibility, stability, mechanisms of action and clinical data.
- List of each standards that have been applied (the mandatory one ISO 13485 and the rest that might apply)
- The information regarding post-marketing surveillance and pharmacovigilance.

Nanoluxe uses nanomaterials and their regulation is not as straightforward as other types of devices. In fact, the rule that applies for these types of devices is rule number 19. Rule 19 belongs to one of the most recent rules added for special cases and it is regarding *"Devices consisting or incorporating nanomaterials"*. Within this rule, there is a further classification into three different classes. If the nanomaterial is present in high or medium potential internal exposure then it is Class III, if present in low

potential for internal exposure then it is Class IIb, if the potential for internal exposure is negligible then it is Class IIa.

As it was stated in the pricing policy and strategy, the nano-tag will be put into different types of devices. For implantable devices that go into the human body such as implants and prosthesis between others, then it is present in high or medium potential for internal exposure, making it fall into the Class III category. In the case of other medical equipment such as blood sugar monitoring systems or other IVDs that can have a low potential for internal exposure, then it would be considered Class IIb. When placed in the package of medical products or pharmaceuticals, then they have a negligible potential for internal expousure and they would be categorized as Class IIa.

For devices that contain nanomaterials there are additional requirements, the European Medicines Agency (EMA) or a national competent authority for medicinal products is consulted to evaluate certain medical devices that are combined with a medicinal product. Furthermore, the new EU regulation on medical devices that became applicable in the spring of 2020 contains specific requirements on devices incorporating or consisting of nanomaterials. The main one is that, under this regulation, special attention shall be given to reduce, as far as possible, any risks linked to the size and the properties of nanoparticles which are or can be released into the user's body. Those devices that are categorized as Class III are subject to stricter evaluation procedures.

There is also an ISO standard that must be fulfilled that is tightly related to the biocompatibility assessment. The ISO/TR 10993-22:2017 describes considerations for the biological evaluation of medical devices that are composed of or contain nanomaterials. ISO/TR 10993-22:2017 include considerations on several aspects such as the characterization of the nanomaterials and the risk assessment.

Apart from the regulation of the technology alone, lately the ISO standards have applied also to the anti-counterfeiting field. There are specifications that the anti-counterfeit technologies must comply with the ISO 22383:2020 – *Security and resilience – Authenticity, integrity and trust for products and documents – Guidelines for the selection and performance evaluation of authentication solutions for material goods.* According to this Standard, the key aspects that will define the most convenient authentication solutions, are: an assessment of the counterfeiting-related risks, the context of implementation and usage, and technical, logistic and financial criteria. These factors give the basis for determining the performance requirements for authentication elements and solutions, and for assessing their effectiveness.

3. CONCLUSIONS

The apparition of new trade routes and E-commerce are some of the main reasons behind the significant increase in counterfeit products globally. Several types of anti-counterfeit technologies are in the market, but there are quite a few of them that have the characteristics that Nanoluxe presents.

The main market niche for Nanoluxe within the medical industry is in the implantable medical devices, some types of medical equipment and IVDs. The implantable medical devices is a field that is still poorly protected by technologies and at the same time, feasible counterfeit threats are an ever-present phenomenon. The government and regulatory bodies have imposed very demanding regulations as a result of several scandals that have taken place in the past. However, the shift in responsibility from the government and regulatory bodies to the manufacturers is making the need for new and more adaptable technologies more evident than ever. The market niche of implantable devices is quite inaccessible for other long-established competitors as they can only offer a solution placed in the package. Additionally, another positive aspect about this market niche is that the patient as well is quite worried about the possible negative outcomes that a substandard implant or prosthesis can pose to their own health. This consumer awareness allows a small increase in the price as an exchange for a trustworthy system that can trace the origin and different touch-points that the implant has been to. The only barrier to this market niche is the fact that the regulatory path is more strict. However, this allows Nanoluxe to set higher prices for these types of products.

Another market niche that can be very profitable include some IVDs systems such as measurement devices that are often targeted by counterfeiters. The glucose monitoring devices are being falsified more over the years and this could lead to very serious health problems for diabetic patients. These types of devices' manufacturers might be interested in applying the Nanoluxe technology in order to maintain brand integrity and reputation.The medical industry has several market drivers such as the aging population or the highest prevalence of chronic diseases that make this industry quite attractive for Nanoluxe. Along these lines, the pricing policy shows that it is possible to make high revenues in each of the four categories that have been determined, if the pricing strategy adapts to each of these market's needs. The anti-counterfeit packaging market is quite consolidated, but it can still work for Nanoluxe because of the high and growing demand for these types of technologies, although it must not be the main focus. The high competition in the USA, make the European market a better option of entry as the government and other regulatory and non-governmental organizations are promoting the almost mandatory obligation to add a tracking system to almost all medical products, making the demand grow at a very high rate.

In conclusion, there are several external factors that make the entry to this market quite attractive for Nanoluxe. The increase in life expectancy is leading to the manufacturing of more medical devices to fulfill the patient's needs, as more chronic illnesses appear. The rise of COVID-19 has made even more evident the problem with counterfeiting, as millions of dollars in worth of products have been seized during this last year due to their falsification. This has constituted a wake up call for both governments and companies to keep on investing in novel technologies to fight counterfeit. Nanoluxe has some interesting features that have make a room within this huge market for his feasible success.

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