

Legally Privileged Attorney Work Product

MEMORANDUM

Legal Opinion on the Best Possible Means and Digital Tools for Fazinger to Review and Implement in the Online Battle against Counterfeit *Dimiflu* throughout the World.

Sophie Barnerias

I have been asked as the in-house Intellectual Property Legal Counsel to provide FAZINGER with in-depth recommendations on best to protect the company's pharmaceuticals internationally against the current onslaught of counterfeit product. The company has just launched its new product – Dimiflu – a medicine intended to cure the flu throughout the world. This memorandum will address the various online challenges faced by the company in selling Dimiflu globally and will examine the best possible digital strategies needed to achieve a safe and successful supply and current launch of its new pharmaceutical product.

I should note that in benchmarking this study with GlaxoSmithKline¹, the City of London Police (Cyber Crimes Unit) and Alibaba, the following "present and clear dangers" for sales on the Internet are crucial to highlight: Digitalisation has changed the rules of the game for pharmaceutical manufacturers, governments and counterfeiters. The Internet has exponentially increased the opportunities to falsify and sell counterfeit drugs to consumers. Close voluntary cooperation with Internet players (especially web and social media platforms) and cyber law enforcement authorities, and the use of innovative, state-of-the-art technologies are going to be the determinative factors to win the battle against online counterfeiters. Consequently, based on the legal and factual analysis undertaken in this study and opinion, only a holistic strategy will enable FAZINGER to become the leader in our marketplace and to be seen as the model for social changes vis-à-vis medicines by safeguarding online distribution on an international basis.

Accordingly, addressing the sale of counterfeits on the Internet requires a number of key strategies:

1. Embrace Blockchain technology and become the leading actor in developing projects.

A trustworthy and transparent supply chain is a fundamental aspect of our strategy. Blockchain technology allows FAZINGER to remove costly intermediaries and shift toward a tighter and controlled network with limited investment.

2. Be an early adopter of the European Directive on serialisation.

¹ Contributions from different visits at the Cyber Crimes Unit from the City of London Police (2018-05-31) and Alibaba (2018-06-01) and interview of Jenny Barker from GlaxoSmithKline (2018-03-23).



As a leader, FAZINGER may want to be on top of the legal requirements of the European Union before the given deadline in 2019. The earlier FAZINGER implements serialisation, the easier we will compete with the US market. FAZINGER will start a group dynamic amongst European pharmaceutical companies and become the leading example in terms of a regulating framework.

3. Maintain friendly but tight relationships and collaborations with the online marketplaces selling *Dimiflu*.

Because the legislative framework is not always favourable to trade mark owners, I suggest maintaining the support of the various players in the digital world. They will be our best allies to limit the number of rogue sellers on their platforms as the outcome of a Notice and Take Down action is in the hands of online websites.

4. Work hand in hand with law enforcement authorities.

Seizures of counterfeit product (especially when public health and safety is at stake) and arrests of dishonest players are the prerogatives of the police (Cyber Crimes Unit of the City of London Police for example). A close and constant working relationship will significantly increase the chances to stop online counterfeiters and to deter criminal networks that could damage the brand from other examples noticed during this study.

5. Support the international and local pharmaceutical community

FAZINGER should be one of the major actors in the battle against online counterfeits. Sharing FAZINGER's solutions and knowledge to build a strong reputation amongst the industry is a long-term investment that will be rewarded with respect from other actors and potential future partnerships.

6. Boost FAZINGER'S image and rebuild the pharmaceutical industry's reputation

Lack of knowledge and distrust are the enemies to our success. Consumers will blame FAZINGER for the lack of results or serious (and potentially life-threatening) side effects they may suffer when using counterfeit drugs. FAZINGER may want to implement international training for health professionals and educational measures to make sure that people will associate FAZINGER with safety and reliability.

7. Be friends with the millennials

Being the number one pharmaceutical market player in terms of technology will help FAZINGER enormously in communicating creative and easily accessible messages. Educating consumers in order to change social behaviours towards medicines must be done via the channels they use daily and with the help of influencers.

8. Adapt your speech according to the public

The motive to buy fake drugs differs from countries. FAZINGER may want to highlight the dangers of buying counterfeits in developing countries where consumers might not have the financial means to get *Dimiflu*. On the other side, FAZINGER should inform the public in developing countries that they support criminal activities by purchasing low-cost replicas.

I – CRUCIAL MONITORING OF THE SUPPLY CHAIN WITH MODERN TECHNOLOGIES

Different technologies can provide the drugs with track-and-trace features from the production until its final delivery to the end-user. Although such techniques are financially burdensome, new technologies are being developed and promise valuable protection as well as effective traceability of the drug.

A) Blockchain: innovative technology

Blockchain technology is a distributed ledger technology (DLT) which, through algorithms and digital encryption, relies on a decentralised transaction of shared copies of a single information held by all the participants. It is replicated across a large network within which all the participants set up common rules that can be amended only with the whole network's agreement. In a nutshell, this new technology can help with the authenticated track-and-trace of product in the supply chain (*see Appendices 1 and 2*).

1. Tracking and tracing Dimiflu from production to delivery

The main issue of our pharmaceutical industry is the **weak traceability of medicines in the supply chain**. Once distributed outside the group, FAZINGER loses control over the product, a phenomenon which has been dramatically accentuated by digitalisation.

Blockchain is already used in the diamond industry or by food sellers to track the origin of the products². Alibaba is experimenting a first pilot of blockchain-based food tracking service to combat food fraud³. Pharmaceuticals could benefit from the blockchain-tracking system by being stamped with an electronic serial number that is digitised in the Blockchain. A digital passport assigned to the product can help to track the journey of the drug from its

³ Danielle Long, 'Alibaba launches blockchain technology to improve supply chain integrity and enhance trust in platform' (The Drum, 30 april 2018) <u>http://www.thedrum.com/news/2018/04/30/alibaba-launches-blockchain-technology-improve-supply-chain-integrity-and-enhance</u> accessed 1 August 2018. Alibaba's initiative called 'Food Trust Framework' is intended to enhance product authenticity and safety. Trials on fish oil and Anchor dairy products purchased on the e-commerce platform are currently on-going and could expand to the global supply chain.



² Jeff Hohn Roberts, 'Big Pharma Turns to Blockchain to Track Meds'(Fortune, 21 September 2017) http://fortune.com/2017/09/21/pharma-blockchain/ accessed 19 July 2018.

manufacturing to the hands of end-users. Each transaction is recorded and all participants must accurately validate the reception of the products and update online any data about the products (date received, number of days in storage, date of shipping)⁴. It is a **great archiving tool by which manufacturers, packagers, wholesale distributors, hospitals, and even the end-customer contribute**. Yet, they all need cryptographic permission to participate, with a key, which ensures a safe channel and a greater monitoring of the community.

With the help of Blockchain technology, FAZINGER would ensure a **greater protection** of *Dimiflu* and its packaging. Whether you want to keep the chain private or public, the information stored in the ledger can remain confidential. Counterfeiters cannot enter the supply chain unless they hack and enter each participant's copy, which is unlikely to succeed. The fact that the information is no longer centralised provides a great incentive and revolutionises the current supply chain process⁵.

In addition, unlike serialisation, Blockchain allows for a **full track-and-trace** everywhere. From a limited internal management, FAZINGER would expand its **control** over *Dimiflu* once diffused outside the group. Harmonising the procedures to authenticate products in every country reduces costs when adapting to the different legislations. The EU will adopt an end-to-end verification system where wholesale distributors authenticate the product before the patient's purchase. In the US, the product will be tracked at different stages throughout the journey of the product⁶.

Some of FAZINGER's competitors are already experimenting with the technology, notably to verify the existence of patents and their use in commerce⁷. Projects such as the MediLedger employ Blockchain technology to reduce counterfeits in the supply chain and to

⁶ Nicholas Basta, 'Traceability end-of-year update ' (Pharmaceutical Commerce, 13 November 2017) <u>http://pharmaceuticalcommerce.com/information-technology/traceability-end-year-update/</u> accessed 1 August 2018.



⁴ Victoria Birch, James Aillieu, Lara White, 'Blockchain technology: application in life sciences and healthcare sectors' (*Nortonrosefulbrightcom*, August 2017)

http://www.nortonrosefulbright.com/knowledge/publications/149475/blockchain-technology-application-in-lifesciences-and-healthcare-sectors accessed 13 June 2018

⁵ Hiroshi Sheraton and Birgit Clark, 'Blockchain and IP crystal ball-gazing or real opportunity '[october 2017] PLC Magazine

help companies to comply with the Drug Supply Chain Security Act (DSCSA) regulations⁸. Blockchain-based solutions attract particular interest in various countries⁹ even if it still requires further developments and certainty as to the solutions it can provide in terms of counterfeited drugs.

As FAZINGER aims to be one of the international leaders, I suggest we consider being part of the MediLedger or similar projects. From this, FAZINGER would **benefit from compliancy with track-and-trace regulations** by **transforming our current system into a blockchain-based platform**. FAZINGER would also **improve its business operation at a lower cost**.

2. Reinforcing intellectual property acquisitions

Intellectual property rights are the most valuable assets of your company. This means that managing and protecting them is critical to the success of FAZINGER. Therefore, our main objective is to ensure that we have accurate and authenticated knowledge of FAZINGER's Intellectual Property Rights proper registration and use.

Smart contracts¹⁰ will bring clarity into our business structure (*see Appendix 3*). By registering the subject of intellectual property in the Blockchain, we can secure ownership evidence on a common channel where all the participants easily communicate, share information, and achieve transactions. Registrations, licences and assignments that are shared on the chain cannot be changed without the consent or notification of all the participants. Although such registration systems are at an early stage, there seems to be much promise in this area to seriously be considered.

¹⁰ Birgit Clark and Ruth Burstall '*Blockchain, IP and the pharma industry—how distributed ledger technologies can help secure the pharma supply chain*' Journal of Intellectual Property Law & Practice, 2018, Vol. 13, No. 7 Smart contract: computerised transaction protocols that execute the terms of a contract automatically, without the need for third parties.



⁸ Webflowcom, 'The MediLedger Project 2017 Progress Report' (Webflowcom, February

²⁰¹⁸⁾ https://uploadsssl.webflow.com/59f37d05831e85000160b9b4/5aaadbf85eb6cd21e9f0a73b_MediLedger 2017 Progress Report.pdf accessed 3 July 2018

⁹ Marina Niforos, 'Beyond Fintech: Leveraging Blockchain for More Sustainable and Inclusive Supply Chains' [2017] Blockchain Opportunities for Private Enterprises in Emerging Markets 48-50 - Deloitte developed Rubix in Canada and iSolve in the US has created BlockRx to work with pharmaceutical companies on Blockchain-based solutions to improve drugs traceability. In the UK, Blockverify provides an easy authentication mechanism.

They are very interesting alternatives to classic agreements as they remove intermediaries' costs and enhance visibility in the whole process. This is equally a great tool to certificate FAZINGER'S ownership of IP assets and fear less about infringement claims. To this end, it will be a great evidentiary tool to prepare a strong defence and show prior use of a trade mark or patent of a medicine as Blockchain archives every use of rights.

3. Managing the stocks of Dimiflu and reducing losses

The pharmaceutical supply chain has many layers which makes it complex and difficult to monitor in such a heavily regulated framework. Product Lifecycle Management (PLM) is the current challenge for the pharmaceutical industry. Counterfeiters take advantage of loose stock management by repackaging outdated medicines before putting them back on the market at a lower price.

Blockchain indexes the exact amount of medicines released and archives information about expiry date for each of them. As a result, FAZINGER will be able to effectively manage stock inventories, and get a clearer view over Dimiflu's life cycle. With an improved control over the quantity and quality of the products both internally and externally, FAZINGER can outsource costs. This solution is promising to regulate potential shortages crises that can have dramatic outcomes in developing countries¹¹.

4. Supervising the actors of the supply chain

Globalisation increased the number of physical transactions and international expenditures¹² that are financially burdensome to the pharmaceutical industry. Moreover, multiple changes of custody create structural fragilities that become opportunities for fraud and corruption. Indeed, the components of Dimiflu might be shipped from China to

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¹¹ Peter Behner, Marie-Lyn Hecht and Fabian Wahl: 'Fighting counterfeit pharmaceuticals: New defenses for an underestimated - and growing - menace' (Pwccom, 29th June 2917)

https://www.strategyand.pwc.com/reports/counterfeit-pharmaceuticals accessed 13 June 2018 ¹² Eric Przyswa, 'Contrefaçons de médicaments et organisations criminelles ' [2013] Institut International de Recherche Anti Contrefaçon de Médicaments (IRACM). The Wuppertal case involved two American sites settled in Holland and Israel. The payment would orientate the consumer through a third site hosted in Israel. The money would be transferred to a band in Panama. In addition, counterfeits were manufactured in China before being stocked in Italy.

Canada for its production, while it is stocked in Italy and sold in France. In addition, online sales of *Dimiflu* might be advertised as coming from Canada and involve a bank located in Ireland.

Blockchain **removes the number of layers in the supply chain** and improves the online environment security by ensuring trusted communication and message authentication where all the participants of the chain simultaneously receive a notification once a product is put on the digital platform¹³. Non-identified goods are carefully filtered so as **parallel imports and second-hand goods that can be better controlled**.

As **maintenance can be done at a lower cost**, unlike serialisation, FAZINGER will **save costs by curtailing operational expenditures** involving shipping logistic; chain managements companies¹⁴ or the maintenance and due diligence costs. This also gives hope for secondary care environment where **loose authentication practices** are common practice.¹⁵ Blockchain is a great asset for developing countries where corruption may impede cooperation of health care professionals who fear for reprisals when divulging counterfeit products. FAZINGER could potentially lead with a social change initiative in this area as Blockchain acts as a tool to **reduce the incentive of corruption within a whole system**¹⁶.

5. Improving Dimiflu's quality

A considerable part of the pharmaceutical industry's budget is dedicated to the fight against counterfeits. Nonetheless, **counterfeiters always find a way to improve their copying techniques** which means that FAZINGER has to invest even more to enhance technological safety. You may recall, that FAZINGER recently experienced this with a

https://pharmaphorum.com/views-and-analysis/ai-and-blockchain-corruption-big-pharma/accessed 13 June 2018



¹³ Gunjan Bhardwaj, 'Why pharma's manufacturing supply chain needs Blockchain innovation' (*Pharmaphorum*, 17th April 2018)

https://pharmaphorum.com/views-and-analysis/pharmas-manufacturing-supply-chain-needs-blockchaininnovation/ accessed 13 June 2018

¹⁴ Gunjan Bhardwaj, 'Five use cases for Blockchain in pharma'(*Pharmaphorum*, 25th April 2018)

https://pharmaphorum.com/views-and-analysis/five-use-cases-for-blockchain-in-pharma/ accessed 13 June 2018 ¹⁵ Bernard Naughton and Dr David Brindley: 'Detecting counterfeit medicines' (Oxford Science Blog, 27 January 2017) <u>http://www.ox.ac.uk/news/science-blog/detecting-counterfeit-medicines</u> accessed 14 June 2018

They produced a study showing the effectiveness of medicine authentication technology and the rate of product recalled as being counterfeits. About 4,000 medicines were serialised using a secure external database. They found that despite a technology's technical detection rate of 100%, only 66.3% of the medicines were authenticated in practice because not all medicines were scanned.

¹⁶ Gunjan Bhardwaj, 'How AI and Blockchain can reduce corruption in Big Pharma (*Pharmaphorum*, 31st May 2018)

dangerously close copy of one of our cancer-fighting medication that contained chalk and starch, causing patients to have adverse reactions.

With costs saved from cutting operational expenditures, FAZINGER can give more weight to *Dimiflu's* quality checks and technology implementations. You should note that Blockchain is a long-term investment that **does not require expensive infrastructures or maintenance.**

Furthermore, Blockchain is a secure platform that can be used as a sharing forum. **Health professionals and even patients could contribute to the improvement of medicines** by giving their **feedback** on *Dimiflu*. Potential adverse effects can be immediately notified to FAZINGER.

6. Improving consumer's healthcare

The pharmaceutical industry suffers from a lack of trust and credibility¹⁷. We should aim at restoring **communication and transparency amongst participants.**

Blockchain has a great potential to improve the healthcare system in general. In addition, to unify the supply chain, it can provide accurate and appropriate sharing of patient's information across different health professionals. The European General Data Protection Regulation challenges businesses' policies in terms of data privacy. Thus, involving directly the patient in the process allows FAZINGER to meet the EU's requirements for a clear consent of the individual and transform social behaviour towards medicines.

ScriptDrop is an example of the full Blockchain's potential in that regard¹⁸. This platform ensures patient's compliance with their medication prescription and works as a channel for greater communication amongst care providers. ScriptDrop envisages a rewarding token system that would pay a portion of patient's prescription in exchange for the access to their data.

https://www.forbes.com/sites/matthunckler/2017/10/09/scriptdrop-leverages-blockchain-to-combat-300-billioncost-of-prescription-drug-abandonment/ accessed 1 August 2018



¹⁷ Ibid 15

¹⁸ Matt Hunckler, 'ScriptDrop Leverages Blockchain To Combat \$300 Billion Cost of Prescription Drug Abandonment' (Forbes, 9th october 2017)

FAZINGER would reduce costs in terms of drug wastage and administrative expenditure as digital prescriptions can be delivered on the platform. Furthermore, it will **put an end to online alteration of the number of products** which is a common fraud in the US¹⁹.

Although yet to be developed, Blockchain technology seems to be a future development for FAZINGER not only **to prevent counterfeits but also as a major change in our operating business**. That is why I suggest to consider it with great attention as to its all range of possibilities. Unsurprisingly, it attracts interest in many fields other than pharmaceuticals that share common issues: the need for traceability and transparency through the supply chain and an increased products' safety. I believe, Mr Morris, that an early investment in Blockchain technology is essential to **maintain a high-ranking position and to differentiate us from our competitors**. Furthermore, it will not cost much in terms of maintenance once implemented, unlike serialisation or mobile technology.

Although promising in various ways, **Blockchain suffers from uncertainties in terms of governance, legal and organisational obstacles**. This technology is not internationally harmonised in terms of legislation and is still experimented at trial phases. Thus, it is important to examine with great care the marketplaces of the online websites to avoid litigation and restrictions from stricter jurisdictions and how the various legal frameworks will evolve in the coming years – which I will of course do. Keep in mind that Blockchain will change your business structure but its implementation will be done over time, as any technology.

At the international level is where you want to make the difference. Blockchain is certainly a promising innovation in the pharmaceutical industry but it requires an openminded and dynamic professional team. I suggest the **creation of a representative working group (The Blockchain Task Force) that will spread the knowledge and skills** required for Blockchain within FAZINGER. Thus, all the different subsidiaries would get the same level of competence. The strength of FAZINGER should be in the ability to harness the opportunities of Blockchain and other new technologies in the world.

¹⁹ Financemagnates, 'How Blockchain Can Reduce Waste for Pharmaceutical Companies ' (Finance Magnates, 16 January 2018) <u>https://www.financemagnates.com/thought-leadership/blockchain-can-reduce-waste-pharmaceutical-companies</u>/ accessed 15 June 2018



B) Serialisation: advanced technology

Serialisation consists of assigning a unique identifier on the packaging of the product that is then checked by scanning the item and comparing it to the database where the identifier is stored. The use of linear, two-dimensional, or radio frequency identification coding allows manufacturers to trace the product throughout the supply chain (*see Appendix 4*). Serialisation could help us at FAZINGER to:

- <u>Improve visibility of stocks</u>: a clear-cut traceability would allow FAZINGER to increase the number of channels to sell *Dimiflu*. Manufacturers must serialise with 2D barcodes, these contain precious information relating to Global Trade Item Number (GTIN), expiration date, batch or lot number and serial number.
- <u>Gather valuable analytics</u>: serialisation is a useful tool to collect data about patient's behaviour, geographical patterns and shortages thanks to a Global Positioning System (GPS).
- 3. <u>Efficient recall tool</u>: with more accurate information about the product, serialisation allows efficient batch recalls by using cloud-based repertoire.
- Systems thinking: serialisation works on the basis of various subsystems within each country and for each manufacturer. Analysing these subsystems helps FAZINGER to tailor its decision-making to answer different needs.

Although **initiatives to implement serialisation have been undertaken in many states** such as Belgium, Italy, Turkey, China, South Korea, Brazil, India and Argentina, **there is no international harmonisation**. The European Union's Falsified Medicines Directive (FDM)²⁰ expects manufacturers to have an authentication process and track-and-trace methods by 2019. In the US, manufacturers are already required to use serialisation since 2017, under the

²⁰ See the Commission delegated regulation (EU) 2016/161 of 2 October 2015 supplementing Directive 2001/83/EC of the European Parliament and of the Council by laying down detailed rules for the safety features appearing on the packaging of medicinal products for human use



Drug Supply Chain Security act²¹. The European serialisation relies on item-level serialisation and is done through national and regional databases with only one authentication at dispensation time. On the other hand, the US authentication is compulsory at any change of custody allowing constant sharing of data amongst intermediaries. This means that a product is only controlled at certain points when there is a change of custody but a product may be moved to different distribution centres without being controlled. Different locations mean different opportunities for injection of fake drugs.

Although the pharmaceutical industry supports the use of harmonised and international standards to identify the products²² the heterogeneous regulations make companies' control over medicines even more complex once the products are released. Indeed, **different serialisation standards lead to fragmented verifications** at the different borders during the journey of the product.

In light of a lack of harmonisation, I would advise approaching serialisation with great care to face the complexity of diverse serialisation regulations. While this technology brings fresh opportunities to improve transparency across the value chain, FAZINGER will need **interoperability between all the business systems**.

First and foremost, I would recommend FAZINGER to set up a specific internal management strategy:

- Define an overall budget with a detailed timeframe: anticipating future hurdles with serialisation is necessary as pilot projects take time and are very complex. It will help FAZINGER to find solutions before the various implementation deadlines.
- 2) <u>Identify the needs for a new architecture</u>: serialisation requires various upgraded equipment and software to edit the current packaging line. Third-party companies

²² Ifpma, 'Serialization and Product Verification – Helping to Secure the Legal Supply Chain for Greater Patient Safety' (Ifpmaorg, 2014) <u>https://www.ifpma.org/wp-content/uploads/2016/03/Joint-Industry-Position-Paper-on-Serialization-and-Product-Verification-.pdf</u> accessed 5 July 2018



²¹ FDA, 'Product Identifier Requirements Under the Drug Supply Chain Security Act – Compliance Policy Guidance for Industry'(Fdagov, June 2017)

https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM565272.pdf accessed 5 July 2018

like Rockwell Automation can provide assistance to implement modular and scalable serialisation systems into FAZINGER's existing production lines²³.

3) <u>Set up cross-functional team management</u>: all the various departments involved in the implementation of serialisation within FAZINGER will have to tighten communication amongst each other to ensure the success of the initiative.

In addition to a careful control of the internal stakeholders, we should develop FAZINGER's external strategy to leverage additional value to the business by identifying international challenges:

- Determine the geographical reach and the markets: roadmap the priority sites to comply with the emerging regulations on time. FAZINGER must be one step ahead of the national and regional mandates by complying with the European requirements as an early adopter.
- Predict and evaluate the essential investments: it is vital to carefully evaluate and budget the resources needed upfront to implement a serialisation system that would fit the various national systems.
- 3) Identify the right partners to support you financially: a lack of resources to implement serialisation could delay the process and lead to loss-of-sales. Multiple partnerships would ease a seamless implementation and provide worldwide financial and management support.

If serialisation is a new technology for the pharmaceutical industry, Chinese manufacturers have implemented a comprehensive serialisation system to provide a greater safety to dairy products such as infant-formula by laser-marking the tins²⁴. Such success gives hope for *Dimiflu*.

²³ Rockwell Automation, 'Pharmaceutical serialization: A Holistic Approach to Product Tracking and

Traceability' (Rockwell Automation, unknown) <u>https://www.rockwellautomation.com/global/industries/life-sciences/overview.page?pagetitle=Pharmaceutical-Serialization&docid=70836de446032b7247cdf88b5e81d8c1</u> accessed 2 August 2018

²⁴ Matthews, 'Chinese parents get instant confidence on Australian dairy' (Matthews, 14th January 2016) <u>https://www.matthews.com.au/resource-library/updates/recent-news/news-archive/chinese-parents-get-instant-confidence-on-australian-dairy</u> accessed 1 August 2018

¹⁴

However, as we saw serialisation does not only impact the packaging lines but the whole structure of FAZINGER's business as it requires new equipment for the packaging line; the integration of new software to handle even more data and cross-functional management team. To successfully cope with the various serialisation requirements, FAZINGER will have to put a lot of effort beforehand as there is a lot of ground to cover.

C) Mobile technology: democratic technology

The use of software built in the sensors, cameras, and connection to a GPS can work as **authentication**, **track and trace and pill image recognition tools**²⁵. Simultaneously connected to Internet platforms or cloud-based services, mobile devices allow for **instantaneous analysis of the product** to check the status of the medicine by receiving short message services (SMS), code scanning or image capture (*see Appendix 5*).

Mobile healthcare applications are valuable as they complement track-and-trace technologies such as serialisation and Blockchain. FAZINGER could promote its healthcare system and find other ways to promote the brand:

- <u>Improve patients monitoring</u>: FAZINGER's mobile application would assist patients in their treatment on a regular basis, especially for patients suffering from diabetes for example, where they need regular checking at specific hours. The application would send reminders to the patient. Such an example can be transposed to *Dimiflu* if we imagine that the patient has been prescribed to use it for a week. Once the length of treatment is entered into the settings, the application would send a daily reminder.
- <u>Get direct patient's feedback:</u> with the help of a user-friendly and intuitive mobile application specifically designed for FAZINGER's patients, consumers will provide data that can be analysed by the company for the development of future products and new ways of revenues.

²⁵ Tim K. Mackey & Nayar Gaurvika (2017) A review of existing and emerging digital technologies to combat the global trade in fake medicines. Examples of such services: mPedigree's in 2005 or Authenticateit in 2016.



Even though such technology is attractive, as it **requires less infrastructure and engages consumers by being user-friendly**, keep in mind, Mr Morris, that it **relies on the participation of patients and pharmacists** who may not be aware of such tools or not willing to spend time using it. In addition, there is a multiplicity of privately owned services that interact in a similar market. Thus, **a risk of fragmentation of the information** or a disparate data source may impede the success of the mobile technology.

Nonetheless, this **tool and approach can also help to democratize a public awareness drive** which can only help our cause with consumers of our pharmaceuticals like *Dimiflu*. While patients become active participants in the fight against pharmaceuticals, FAZINGER enjoys the benefits from marketers and sales perspective.

II – ENFORCING FAZINGER'S INTELLECTUAL PROPERTY RIGHTS

The second part of FAZINGER's strategy must focus on the protection of our trade marks which are one of our most valuable assets. Once *Dimiflu* will be put on the online market, replicas will appear on multiple illegal websites that are difficult to shut down. Indeed, the Internet provides greater anonymity to counterfeiters and allows them to disappear and reappear so quickly that it has been dubbed as a "whack-a-mole" effect²⁶. It is further complicated by the huge volume and velocity of counterfeits that can be found online (*see Appendix* 6).

In addition, the lack of an international legal framework to fight against online counterfeit goods renders court actions unpredictable. I would suggest that we **avoid court actions** as they are costly for FAZINGER and will be of no significant help to face the sheer volume of infringements online. Cooperation and collaboration are the keywords in the second part of our strategy.

A) Self-regulatory and voluntary, collaborative measures

Voluntary and self-regulatory measures will allow FAZINGER to reduce the financial burden of litigation. It is a quicker answer to the velocity and the sheer number of counterfeits online. Furthermore, if FAZINGER loses the case, you may have to bear the entire costs in some jurisdictions.

1. Internet Service Providers' secondary liability

²⁶ Frederick Mostert, 'Study on approaches to online trademark infringements' in WIPO/ACE/12/9 REV



Some legal frameworks are not pharmaceutical industry-friendly and FAZINGER will be the only one to pay the costs to protect its brand. There is **no uniform international rule regarding secondary liability of online marketplaces.** National courts have given some guidance as to what the responsibility of ISPs is and to what extent intellectual right owners can obtain damages for their action or inaction.

The US Supreme Court provides protection to online intermediaries and provided in *Tiffany Inc v eBay*²⁷ that e-commerce platforms like eBay cannot be held liable for trademark infringement even if they had a general knowledge about the infringement. It will be, to a large degree, the responsibility of FAZINGER to prevent any sales of fake versions of *Dimiflu*.

Standing in contrast, the French decision $LVMH v eBay^{28}$ considered that eBay was liable for negligence and did not take the appropriate steps to put an end to the online infringement on its platform. Thus, in France, trade mark holders can require greater help or impose more obligations over intermediaries when it is clear that they store and allow the sale of fake drugs on their platforms.

The Court of Justice of the European Union (CJEU) has provided guidance on the responsibility of the intermediaries in light of the article 11 of the Enforcement Directive²⁹ and $14(1)(b)^{30}$ of the E-commerce Directive in the case of *l'Oréal v eBay*³¹. Accordingly, an operator will benefit from 'safe harbour' protection if it does not play an active role in assisting or optimising the offers of sale or by providing knowledge as to sales offered on the platform³². However, the Court's statement did not give a distinct framework of ISPs liability and made clear that e-commerce platforms could still be subject to injunctions to stop infringements.

In conclusion, the e-commerce platforms' liability regime for online infringement is not fully clear and legally uncertain for our business planning purposes. I suggest that



²⁷ Tiffany Inc. v. eBay Inc., 600 F.3d 93 (2d Cir. 2010)

²⁸ SA Louis Vuitton Malletier v. eBay Inc., Cour de cassation [Cass.]

²⁹ Directive 2004/48/EC of the European Parliament and of the Council of 29 April 2004 on the enforcement of intellectual property rights (Enforcement Directive), article 11.

³⁰ Directive 2000/31/EC of the European Parliament and of the Council of 8 June 2000 on certain legal aspects of information society services, in particular, electronic commerce, in the Internal Market (E-Commerce Directive), article 14(1)(b).

³¹ L'Oréal SA and others v eBay International AG and others, Case C-324/09, 12 July 2011

³² L'Oréal v eBay, paragraph 116

I, as IP Counsel, **pay very close attention to the various websites policies** and jurisdictions' approach towards online intermediary liability before deciding which partnerships we, at FAZINGER, wish to develop. Keep in mind that **an aggressive strategy towards intermediaries is not sustainable long-term, it will be costly** to FAZINGER and bear few results as some multinational brand owners have discovered.

It is worth noting that Alibaba Anti-Counterfeiting Alliance (AACA) reunites 30 brands to join forces and effectively monitor and takedown reported replicas sold on the Alibaba's marketplaces³³. **Working with online platforms is crucial** and FAZINGER could benefit greatly from their help. Alibaba really engaged in anti-counterfeiting actions by suing sellers of fake Swarovski's watches on Taobao³⁴. If you allow me, I could start the process to set up a partnership with Alibaba, on the behalf of FAZINGER to anticipate the protection of *Dimiflu* over one of the major e-commerce platform.

2. Notice and takedown procedures

Notice and Takedown procedures (NTD)³⁵ are common practice in the field. However, they are considered as **soft law measures as they are not always strictly regulated under national legislation and the amount of commitment to help fighting counterfeits depends on each marketplace³⁶. Nonetheless, codes of conduct at EU Community level have been signed by major online marketplaces such as eBay, Amazon, Alibaba in light of the E-commerce Directive³⁷. The purpose of such contribution was to implement common practices and to enhance the fight against counterfeit online and NTD procedures. However, it is relying mainly on the intent of the signatories** and it is suggested that in terms of pharmaceuticals, it has not been very effective. Yet, some companies like Alibaba have friendly right holders' policy to help them fighting online counterfeits and assist to do so. By

³⁵ Knud Wallberg, *Notice and takedown of counterfeit goods in the Digital Single Market: a balancing of fundamental rights*' [2017]12(11) Journal of Intellectual Property Law and Practice 922-936.
³⁶ Alibaba is one of the main platform involved to protect trade mark owner's IP rights by providing great

assistance with their anti-infringement practices and enhancing NTD procedures. ³⁷ See Report from the Commission to the European Parliament and the Council on the functioning of the

Memorandum of understanding on the Sale of Counterfeit Goods via the Internet /* COM/2013/0209 final */



³³ Tom Brennan, 'Alibaba's New IP Advisory Board to Boost Brand Cooperation ' (Alizila, 17 September 2017) <u>https://www.alizila.com/alibabas-new-ip-advisory-board-boost-brand-cooperation/</u> accessed 2 August 2018

³⁴ Arjun Kharpal, 'Alibaba sues sellers of counterfeit goods for the first time after it was blacklisted by the US' (CNBC, 4 January 2017) <u>https://www.cnbc.com/2017/01/04/alibaba-sues-sellers-of-counterfeit-goods-for-the-first-time-after-it-was-blacklisted-by-the-us.html</u>

accessed 2 August 2018

working together, right holders and ISPs can avoid issues of censorship as keywords filtering mechanisms may hamper genuine sellers who could replicate through counter-notice. It would also damage the reputation of both parties as well as discrediting the efficiency of NTD.

Keep in mind Mr. Morris that **NTD procedures**, under the EU legislation, **must also consider ISPs' freedom to conduct business**. The CJEU decision in *UPC Telekabel*³⁸ highlights that operators have decision-making power in the assessment of the NTD and can decide the number of resources they wish to invest to that effect. Furthermore, the Court held that the ISPs, when complying with the injunction, have to balance the interests of the right holders but also internet users' freedom of expression and information³⁹.

Accordingly, I suggest we do our research with great consideration on which potential online pharmacies should sell *Dimiflu* to see how they enforce intellectual property rights and which actions they put in place to curtail any infringement by thirdparty vendors on their platforms.

It is essential for FAZINGER to adopt a cooperative and collaborative behaviour with our different online partners and to maintain solid relationships⁴⁰. An agreement must be set between FAZINGER and the operator and it is your responsibility, as the right holder of *Dimiflu*, to give evidence of the alleged fake product online (a photo or content suggesting a counterfeit)⁴¹. Some other countries may ask for further requirements⁴². Needless to say, I will undertake such evidentiary tasks with your blessing.

3. Blocking injunctions

FAZINGER should consider blocking injunctions if we cannot obtain sufficient protection for our rights through Notice and Takedown. Although the Enforcement

⁴² Christian Ahlert, Chris Marsden and Chester Yung, "How 'Liberty' Disappeared from Cyberspace: The Mystery Shopper Tests Internet Content Self Regulation". NTD in the US are formalised under the Digital Millennium Copyright Act providing a heavier procedure for IP owners.



³⁸ CJEU in UPC Telekabel Wien GmbH v Constantin Film Verleih GmbH [2014] Bus LR 541, [50].

³⁹ Knud Wallberg, 'Notice and takedown of counterfeit goods in the Digital Single Market: a balancing of fundamental rights' [2017]12(11) Journal of Intellectual Property Law and Practice 922-936. The author suggests that the approach taken by the CJEU regarding injunctions and the balance of interests could be extended to NTD procedures.

⁴⁰ <u>https://rule.alibaba.com/rule/detail/2049.htm</u>. Alibaba provides an easily accessible platform for brand owners to fill up an NTD procedure.

 ⁴¹ <u>https://ipp.alibabagroup.com/submission.htm</u>. It details the documentation required to further have the possibility to claim for infringement.
⁴² Christian Ahlert, Chris Marsden and Chester Yung, "How 'Liberty' Disappeared from Cyberspace: The

Directive⁴³ is intermediary-friendly with the safe harbour protection, it still gives us only a complementary action. In the UK, the Copyright, Designs and Patents Act (CDPA) does not provide specific provisions for blocking injunctions available to trade mark owners. However, the UK Supreme Court had provided guidance as to the conditions to meet in order to bring an ISP liable for an online infringement. But, the recent reversal by the UK Supreme Court, in the *Cartier* case, has rendered the financial burden of counterfeit fight heavier for brand owners.

The UK Supreme Court held that a blocking injunction may become more and more costly for us, as the right holder, since ISPs may not be obliged to pay the cost of implementing website blocking orders in relation to trade mark infringement. The Court found that online intermediaries are not guilty and should not bear this financial burden but instead, it is the responsibility of right holders⁴⁴.

Such decision reinforces the **necessity for companies to engage in partnerships with every online actor** to obtain help to prevent the purchase of counterfeit or the multiplication of illegal merchants online. Communication with local cybercrime authorities, such as the City of London Police, may prevent costs for injunctions as law enforcement bodies can take actions to help right holders significantly.

B) Cooperation with public and private organisations

As you will notice from this analysis, FAZINGER does not benefit from a large range of legal solutions to protect ourselves from online infringement. The lack of civil and criminal remedies requires a greater need for involvement in international voluntary cooperation to fight counterfeits and a tight collaboration with each player in the market.

1. Collaborating with specialised companies

⁴⁴ Cartier International AG and others v British Telecommunications Plc and another [2018] UKSC 28 [2018] WLR(D) 354



⁴³ See article 8(3) of Directive 2001/29 which provides: 'Member States shall ensure that rights holders are in a position to apply for an injunction against intermediaries whose services are used by a third party to infringe a copyright or related right'.

With online infringement, the main issue is **consumer confusion**. Thousands of online sites try to look genuine by using the brands' logo or name to attract consumers and diverge them from the company's platform. Often, web searching the brand name accompanied by keywords such as 'fake or 'cheap' leads to counterfeits and rogue websites. The in-house legal department of FAZINGER does, unfortunately, at present, not have the skills and resources to deal with constant online monitoring.

Accordingly, I would suggest hiring companies that are specialised in the matter. Such companies can be most helpful to deal with the sheer amount of online sales of fake drugs. MarkMonitor or NetNames possess the technology to monitor and filter all the results and once they spot valuable targets, they take investigation and enforcement measures. They can deactivate domain names at registry level or remove search links⁴⁵. This expertise is important since the increasing availability for registering a domain name⁴⁶ multiplying the threat of rogue websites. Private companies can file a Uniform Domain-Name Dispute-Resolution Policy (UDRP) to complain against registration of infringing domain names for us. As you may know, we recently experienced a problem with the rogue registrations of "dimiflu.cn, dimiflu.edu or dimiflu.fr redirecting customers to malicious sales.

Trading platforms such as Amazon, Alibaba or eBay⁴⁷ **provide great assistance** for brand owners to tackle infringement online by filing online forms to claim infringements. Similarly, cooperative actions taken between FAZINGER and **Payment Service Providers (PSPs) can help to curtail the number of online purchasing and prevent counterfeiters to receive payment from online sales**⁴⁸. For example, Visa has launched voluntarily searches to help brand owners in the payment system processing by allowing victims to fill an online

online' (*Worldtrademarkreviewcom*, 7 February 2017). Paypal, MasterCard, Visa or American Express contribute to the programme RogueBlock.

http://www.worldtrademarkreview.com/Intelligence/Online-Brand-Enforcement/2017/Chapters/Alternativestrategies-for-fighting-counterfeits-online accessed 19 June 2018.



⁴⁵ Stuart Durham, General Manager UK, NetNames, at ialci and Crefovi seminar on "Intellectual property: how to protect, manage & monetize the know-how, intangible capital, brand image and reputation of luxury maisons & fashion brands" in London – 10 February 2015 – YouTube video to be found on:

http://crefovi.com/articles/fashion-law/is-intellectual-property-in-fashion-and-luxury-a-relevant-topic-you-bet/ 46 Nadia Zegze, 'Bad news for brands? It's early days for gTLDs' (The IPKat, 3& March

²⁰¹⁴⁾ http://ipkitten.blogspot.com/2014/03/bad-news-for-brands-its-early-days-for.html accessed 25 June 2018 ⁴⁷ See https://pages.ebay.co.uk/vero/about.html. eBay's Verified Rights Online Program (VeRO) helps IP owners to prevent sellers from illegally marketing, merchandising and selling illegal copies.

⁴⁸ Michal J McCue and Anne Aikman-Scalese, 'Alternative strategies for fighting counterfeits

form or to send emails to report counterfeits⁴⁹. Visa can track a counterfeiter online and send a 'comply or terminate' notice to the counterfeiter.

The important traffic generated through Facebook, Twitter or Instagram incites counterfeiters to post fake advertising links that redirect consumers towards their websites. This phenomenon is stressed with a **lack of regulation regarding the secondary liability of social media and their obligation to monitor such content**. Besides lobby actions to the government for greater sanctions and responsibility, **we should partner up with specialised companies such as BrandBastion**⁵⁰ that will help our legal team to control generated comments posted on FAZINGER's Facebook official page. As an example, BrandBastion analysed 36,000 comments received by 12 luxury brands resulting in 729 counterfeit comments, 94 illicit accounts and over 1,000 spam comments⁵¹. Such striking figures reflect the severe threat over FAZINGER's reputation if *Dimiflu* becomes the new target. In a nutshell, I strongly recommend to adopt a **strategy specifically focused on social media and to consider with great care third-parties specific knowledge.**

2. Participating in international efforts to fight counterfeits

Acting locally is not enough to enforce your rights. Pharmaceutical counterfeits are an international major problem addressed by organisations like the World Customs Organisation, Europol, Interpol, the Organisation for Economic Cooperation and Development (OECD) and other professional health federations.

a) Criminal proceedings and cooperation with law enforcement agencies

Dimiflu could become the next major counterfeit product online. To prevent this, I suggest that we **work closely with national law enforcement bodies** by providing accurate information regarding our product and the actions you take to fight against counterfeits. In the

⁵⁰ <u>https://www.brandbastion.com/adbastion</u>

https://cdn2.hubspot.net/hubfs/2343430/What Luxury Brands Need To Know When on Instagram.pdf accessed 4 August 2018



⁴⁹ Aniket Kesari; Chris Hoofnagle; Damon McCoy, *Deterring Cybercrime: Focus on Intermediaries*, 32 Berkeley Tech. LJ. 1093 (2017)

⁵¹ Brandbastion, 'What luxury brands need to know when on Instagram' (Hubspotnet)

UK, we should collaborate with the City of London Police Intellectual Property Crime Unit (PIPCU) as they will be our best ally to tackle counterfeits⁵². If you agree, I will immediately proceed to set up a working relationship with PIPCU on behalf of FAZINGER.

We should also consider working together with the International Anti-Counterfeiting Coalition (IACC)⁵³, they fight online counterfeiting with the RogueBlock programme⁵⁴. Such action requires the participation of credit card companies to curtail counterfeiters' online sales by stopping the processing of payment. This approach is consistent with the "follow-the-money" principle. Operation Pangea also shows the success of the collaboration between public authorities and private organisations to combat online sales of medicines. ISPs, postal services and financial intermediaries have helped to shut down rogue websites⁵⁵. As an example, Operation Pangea has led to a striking number of 3,584 websites selling fake drugs being taken offline⁵⁶ which is very encouraging for the pharmaceutical industry on an international scale.

b) Codes of conduct

We should also **cooperate with international institutions to attract good press.** To do so, I recommend to **voluntarily support and adopt codes of conduct** prepared by local authorities⁵⁷ or codes of good behaviour and communication of progress⁵⁸ already available

http://www.worldtrademarkreview.com/Intelligence/Online-Brand-Enforcement/2017/Chapters/Alternativestrategies-for-fighting-counterfeits-online accessed 19 June 2018. Since 2012, RogueBlock has led to the termination of 5000 merchant accounts, affecting 200,000 websites.

https://safemedsonline.org/2017/10/operation-pangea-x-successfully-targets-websites-selling-fake-opioidsdangerous-drugs/ accessed 30 August 2018 ⁵⁷ The French Ministry of Industry supports charters to facilitate the prevention of counterfeit drugs on the

³⁷ The French Ministry of Industry supports charters to facilitate the prevention of counterfeit drugs on the internet: 'Charte de lutte contre la contrefaçon sur Internet entre titulaires de droits de propriété industrielle et plateformes de petites annonces' signed by various French online platforms in 2009.



⁵² Ipprotheinternet, 'PIPCU and IACC team up to fight online fakes'(Ipprotheinternet, 18 April 2017) http://www.ipprotheinternet.com/ipprotheinternet/IPProTheInternet_issue_115.pdf accessed 19 June 2018

⁵³ Aniket Kesari, Chris Hoofnagle and Damon McCoy, *Deterring Cybercrime: Focus on Intermediaries*, 32 Berkeley Tech. L.J. 1093 (2017). The IACC is an organisation gathering businesses, law firms, security firms and government organisations to cooperate and fight IP infringement by providing services such as RogueBlock or MarketSafe. This latter is an example of partnership between the IACC and Alibaba to enforce take-down procedures online.

⁵⁴ Michal J McCue and Anne Aikman-Scalese, 'Alternative strategies for fighting counterfeits online' (Worldtrademarkreviewcom, 7 February 2017)

⁵⁵ Interpol, 'Online sale of fake medicines and products targeted in INTERPOL operation' (Interpol, 9 June 2017)

https://www.interpol.int/en/News-and-media/News/2016/N2016-076 accessed 25 June 2018 Pangea IX (2016) is an operation gathering 103 countries. It resulted in 12.2 million seizures of fake drugs and

more than 270,000 medical devices; 4,932 websites shut down; 393 arrests.

⁵⁶ CSIP, 'Operation Pangea X Successfully Targets Websites Selling Fake Opioids and other Dangerous Drugs ' (The Center for Safe Internet Pharmacies (CSIP), 15 October 2017)

from a Human Rights perspective. Pharmaceuticals present similar public order concerns that entitle consumers to obtain information about the actions taken by the companies to ensure a safe delivery of the product. These codes of conduct allow **greater transparency and incentivise brand owners to maintain a level of protection and liability**.

In conclusion, I suggest avoiding an aggressive strategy in terms of enforcing your IP rights. On the contrary, the best way to maintain a low volume of daily online infringement listings is to stay close to online intermediaries and to show active actions taken at an international and local level with the relevant institutions. Investing financial resources to enhance collaboration and cooperation will be rewarded in the long-term. Drug counterfeits are an international health issue that touches all our competitors and we cannot win that battle on our own but only through constant collective action.

⁵⁸ Sorcha MacLeod: *Stuck in the Middle With You?: Alternative Approaches to Realising Accountability for Human Rights Violations by Businesses*. The author talks about Corporate Social Responsibility where companies have obligations in terms of human rights and the environment.



III – DEVELOPING EDUCATION AND PUBLIC AWARENESS

A proportion of counterfeit sales is due to consumer's demand for it. This is usually true for the fashion industry but it is less obvious in the pharmaceutical industry. The **lack of knowledge about fake drugs and their risks for people's lives is the root cause** that manufacturers cannot ignore in their strategy to tackle counterfeits. Economic, social, political issues may lead consumers to purchase the cheaper version of a product without really understanding the risks they undertake. This is especially true in developing countries.

Consequently, the third pillar of our strategy will be to show our impact at ground level and inform the consumers about *Dimiflu*; the risks of self-medication and purchasing fake versions of it.

1. Involving consumers in the battle

Transmitting knowledge is FAZINGER's responsibility. It is not the easiest part of our strategy but with **targeted speech** and **modern tools** used by a large part of the population we will communicate the right ideas in an efficient way and will distinguish FAZINGER from other competitors that may take traditional campaign actions.

a) Educate the public

The **public ignores the percentage of counterfeited drugs** as it is difficult to find reliable numbers on the Internet. Consequently, they do not necessarily pay attention when purchasing online. Furthermore, the **Internet facilitates self-medication** and a concerning amount of **online pharmacies does not require evidence of a prescription** to deliver the product. These issues must be at the core of FAZINGER's campaigns⁵⁹ to **teach consumers where to purchase** their products and **how to identify counterfeits**. With striking numbers and upto-date studies about falsified products, we would get **people's attention as they would feel directly concerned** by the issue. I suggest accompanying figures with photos showing the conditions in which fake medicines are produced (rusted machines, rat poison traces and other dangerous products) (*See Appendices 7, 8 and 9*).

We should expose the variety of products that are counterfeited to show that any kind of medicine can be falsified. The emphasis should be put on the ability of counterfeiters to copy the brand's packaging and to make them look like genuine products which will deceive the consumers. It is important to highlight how counterfeiters tend to deceive and dilute the trust online by using social media or examples of non-genuine domain names or emails and spams. Providing an example of counterfeits by showing two very similar tablets will strike minds as to how similar fake drugs can be towards legitimate products (*see Appendices 10 and 11*).

The Internet has the effect of **democratising criminality** in a way that **people do not fear sanctions** mainly because these are so not important that they do not realise the severity of their actions. **Educating them would prevent secondary infringement** of any individual who takes part in the business of counterfeiting if they realise the severity of the harm to life and potential punishment. Customers buy a product because it is cheaper but do not realise it is a fake drug, and contribute to a fraud on the public. Some customers even purchase counterfeits online and resell them later.⁶⁰

b) Tailoring the campaigns

⁶⁰ See Interpol: pharmaceutical and organised criminal group report. It relates this trend of amateurs athlete and persons involved in bodybuilding that takes part of the supply chain in providing directly counterfeits in the building for members of the club



⁵⁹ Sanofi, 'Fighting Counterfeit Medicines Factsheet ' (Sanoficom, May 2017)

https://www.sanofi.com/media/Project/One-Sanofi-Web/sanofi-com/common/docs/downloadcenter/Fighting Counterfeit Medicines May 2017.pdf accessed 19 June 2018. Sanofi launched a campaign called "Fight the Fake", joined by GSK.

Due to societal differences, **the reason to purchase a fake drug differs between developing and developed countries**. Two types of purchases must be distinguished⁶¹. Nondeceptive counterfeit medicines are purchased by consumers who are willing to obtain a fake product because they cannot afford the genuine drug, for financial reasons. In contrast, consumers will obtain deceptive counterfeits if they genuinely purchased the product thinking it is the original one. Hence, FAZINGER should propose **tailored anti-counterfeit campaigns to a public with different environment needs**.

When speaking to a public that is less concerned with a price difference, we should highlight the following points:

- Using falsified medicines is **life-endangering**, potentially causing death (see Appendix 12)
- Taking part in counterfeiting medicines is illegal and punishable by law
- Buying cheaper versions of legitimate drugs damages the environment
- Counterfeit activity supports human rights violation
- Counterfeit activity is closely connected to terrorism.

On the other hand, when the purchase decision is triggered by economic reasons, campaigns should emphasise the following key aspects:

- Self-medication via online pharmacies entails health risks
- Buying genuine product is a long-term investment for their health.
- Fake drugs lead to the consumption of more products, to compensate the **lack of** effect, and to drug resistance⁶².
- If the price difference is important, so will be the risks of purchasing a fake drug (*see Appendix 13*)

Raising awareness is a **necessary part of the strategy for a long-term diminution of counterfeits**. *Dimiflu* as a cure for the flu is a worldwide target in the counterfeit business. Consequently, it is crucial that FAZINGER adapt the campaigns according to the social needs of the various countries.

⁶² Eric Przyswa, 'Contrefaçons de médicaments et organisations criminelles ' [2013] Institut International de Recherche Anti Contrefaçon de Médicaments (IRACM)



 ⁶¹ Robert C. Bird, '*Counterfeit Drugs: A Global Consumer Perspective*'[2007] 8(3) Wake Forest Intellectual property Law Journal 387-406
⁶² Eric Przyswa, 'Contrefaçons de médicaments et organisations criminelles ' [2013] Institut International de

In addition, we could envisage **putting warning labels on the packaging** to inform consumers about risks of counterfeit in a similar way tobacco packages strike minds about adverse effects of smoking (*See Appendix 14*).

2. Changing consumers' behaviours by using social media

The Internet has facilitated the access to direct-to-consumer advertising (DTCA). DTCA is an important marketing strategy for brand owners. YouTube, Twitter or Facebook have become the ideal forums to sell counterfeits and target specific categories of people for a designated product. Unfortunately, consumers rarely question the veracity of the product purchased online and they cannot inspect the quality of a product⁶³. It is especially true for young people who often make impulsive purchases driven by the speech of people they listen to. The old-world speech coming from the company may not have the expected impact on them. Hence, we need to find alternative ways to communicate our message.

Such tendency is accentuated by the promotion of social media influencers when publicly praising lifestyle drugs or products. This kind of **advertising suffers from misinformation** regarding the product's origin and any risks or potential contraindication to use the product. Nevertheless, they attract a lot of credibility about the product they advertise which may benefit illegal online pharmacies or forums and expose consumers to unaffiliated companies⁶⁴.

But, we should not see social media as an enemy. I suggest working with popular media by using them in a creative way to raise awareness about counterfeits (*See Appendix*

⁶⁴ Tyrawski J and DeAndrea, D. C. (2015), *Pharmaceutical Companies and Their Drugs on Social Media: A Content Analysis of Drug Information on Popular Social Media Sites*. Journal of Medical Internet Research, 17(6), e130.



⁶³ See Sanofi, 'Perceptions of Counterfeit Medicines: Only 12% of Americans Feel They Have Enough Information' (Multivu, 2015)

http://www.multivu.com/players/English/7697951-sanofi-counterfeit-medicines/ accessed 5 July 2018. The study suggests that only 15% of American respondents make a link between counterfeit and medicines while 54% connect it to fashion and 43% with luxury goods.

15). In addition, influencers like Lauren Wasser draw the attention to the dangers of using inadequate products⁶⁵ and **allow brand owners to obtain credibility in their products** and make people aware of the variety of **drugs that may be fake**.

3. Improving online pharmacy verification

National associations provide a list of genuine online pharmacies. The EU has introduced a logo that enables consumers to check if they are dealing with genuine retailers and can access a national list of registered online sellers⁶⁶ (*see Appendix 16*). FAZINGER should, as soon as possible, adopt this **registration system by providing a list on its official** website with links to online pharmacies or marketplaces⁶⁷ where consumers can find *Dimiflu*.

I also suggest **web-based solutions** that allow consumers to **easily verify the legal status** of *Dimiflu* if they purchase online. Such measures include website seals, websites verification services by querying the URL of the online pharmacy or pre-approved legitimate online pharmacy domain names. I have collected a list of these for you Mr. Morris and am happy to send it to you if you so wish.

4. Training health professionals on a regular basis

Health professionals may feel at a distance from manufacturers even though they both belong to the same pharmaceutical industry. A **lack of trust and cooperation are factors to promote bad behaviour and customs.** In order to resolve transparency and accessibility, **representatives of FAZINGER should constantly be working together with health professionals in the various subsidiaries**. See that as another opportunity to get feedback

http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000630.jsp accessed 27 June 2018



⁶⁵ Judith Vonberg and Chelsea Ritschel, 'Model who lost her leg after using tampon has other leg amputated' (The Independent, 15 January 2018)

https://www.independent.co.uk/news/world/americas/lauren-wasser-toxic-shock-syndrome-tampon-legamputated-tampon-tss-infection-a8159401.html accessed 3 July 2018. The model Lauren Wasser lost both of her legs after a tampon-induced toxic shock syndrome. Since this, she is raising campaigns for awareness on social media.

⁶⁶ Directive 2011/62/EU of the European Parliament and of the Council of 8 June 2011 relating to the prevention of the entry into the legal supply chain of falsified medicinal products.

⁶⁷ European medicines agency, 'Buying medicines online' (European Medicines Agency)

from professionals who use *Dimiflu* on a daily basis but also to build relationships of trust between partners.

I recommend **tailored in-house training programs** to ensure an adequate transmission of knowledge and skills and implement anti-counterfeiting measures taken by FAZINGER. We can distinguish ourselves from competitors by adopting a specific training program to educate online platforms and the various intermediaries on how to monitor potential counterfeits of *Dimiflu*. In return, we can possibly ask in return for an arrangement from the **platforms to pro-actively notify FAZINGER about counterfeits** on their platforms⁶⁸.

Conclusion

Globalisation and digitalisation have had a devastating impact for brands owners by providing greater and easier ways for counterfeiters to duplicate and diffuse falsified drugs all over the world. The number of counterfeits has increased exponentially, we cannot expect to fight the battle alone and not with only a severely limited number of measures currently in place at FAZINGER. Through a holistic approach, our company will be able to protect *Dimiflu* against a number of counterfeits.

First of all, the whole life of the product must be monitored and protected with the help of innovative technologies, from its production to the final delivery to the consumer. Serialisation should be implemented at the earliest to comply with the European framework but I recommend to further invest in the new technology: Blockchain. It has a promising future in the pharmaceutical industry as it changes the whole structure of your business. Nonetheless, it will not be implemented before 2023 and legislation might impede its progress. That is why the legal department of FAZINGER should be on top of each national mandate if we want to maintain a leader status.

Second of all, the Internet allows for international communication amongst the pharmaceutical community and gives phenomenal possibilities to control the supply chain of pharmaceuticals. Even if there is a lack of international legislative guidance surrounding

FINAL_sm_final.pdf accessed 15 August 2018.

Alibaba pro-actively monitors NTD requests and in 2017, 95% of them were processed within 24hours. This led to 42% of takedown requests by brand owners.



⁶⁸ Alibaba, 'Alibaba Group 2017 IP rights Protection Annual Report ' (Alizila, May 2018)

http://azcms31.alizila.com/wp-content/uploads/2018/05/Alibaba-Group-PG-Annual-Report-2017-

counterfeits of medicine, considerable efforts are being made and give hope for a better future regarding consumers' health. We should stay involved in research and international/local actions to keep an updated regulatory framework. Common codes of conduct and behaviour towards online infringement aim to put an end to the fragmented current standards, so I suggest to sign these charters to attract good press.

Similarly, working together with online intermediaries is the appropriate and unique way to fight counterfeits on every front. The major online platforms such as Alibaba or eBay are the leaders in the field and should be the model to follow by other websites and social media that are lacking any guidance regarding fake products. Private companies must be part of the battle as well as they have a full range of weapons to reduce the number of counterfeiters and rogue marketplaces.

Finally, constant cooperation with public organisations such as law enforcement authorities and government bodies is a vital aspect of our strategy. As your legal counsel, I could take all the necessary steps to set up working partnerships with important local authorities, such as PIPCU, to grow FAZINGER's connections in various countries.

By following this guidance, we will guarantee a strong shield to *Dimiflu* and contribute greatly to the general war against counterfeit medicines whether online or in the physical world. It will help to make FAZINGER's consumers believe in *Dimiflu* and in our company - as a model for other brands.

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http://crefovi.com/articles/fashion-law/is-intellectual-property-in-fashion-and-luxury-a-relevant-topic-you-bet/

APPENDICES



Appendices 1 & 2 - Infographics illustrating how Blockchain can improve the pharmaceutical industry⁶⁹

https://thepump.jsi.com/how-the-technology-behind-bitcoin-can-strengthen-health-services-protect-patientprivacy-and-improve-trust-in-medicine-quality/ accessed 31 August 2018



⁶⁹ Jsicom, 'How the Technology Behind Bitcoin Can Strengthen Health Services, Protect Patient Privacy, and Improve Trust in Medicine Quality' (Jsicom, April 14, 2017)





Appendix 3 - How smart contracts change the entire healthcare industry⁷⁰

https://medium.com/@vfn.cosmic/disruptive-cryptography-smart-contracts-with-healthcare-blockchainintroducing-healthureum-e04963f18371 accessed 31 August 2018



⁷⁰ Mediumcom, 'Disruptive Cryptography Smart Contracts with Healthcare Blockchain: Introducing Healthureum' (*Medium*, unknown)



1) Generic systems, may be modified for country-specific systems

Appendix 4 – Serialisation system⁷¹



Appendix 5 - Example of mobile phone technology to control packaging⁷²

⁷¹ Nicolás giménez stamminger, 'Driving business value from pharmaceutical serialisation'(European Pharmaceutical Review, 15 February 2017)

https://www.europeanpharmaceuticalreview.com/article/48048/driving-serialisation/ accessed 31 August 2018 ⁷² See slide 26 <u>https://www.slideshare.net/samikshasawant146/anti-counterfeit-packaging</u>





Appendix 6 – Substantial number of search results on Google to buy fake drugs⁷³



Appendix 7 - Laboratories used to counterfeit high brands cosmetics.Traces of mercury and cyanide have been found⁷⁴

⁷⁴ Chris greenwood, 'Warning on fake make-up tainted by CYANIDE and other dangerous chemicals: Counterfeit versions of leading brands are being cooked up by criminals in squalid underground labs' (Dailymail, 18 May 2015)



⁷³ Laurie Garrett, 'Ensuring the Safety and Integrity of the World's Drug, Vaccine and Medicines Supply PART TWO' (Lauriegarrettcom, May 16, 2012)

http://lauriegarrett.com/blog/2012/5/16/ensuring-the-safety-and-integrity-of-the-worlds-drug-vaccine-andmedicines-supply-part-two accessed 31 August 2018 ⁷⁴ Chris greenwood, 'Warning on fake make-up tainted by CYANIDE and other dangerous chemicals:



Appendix 8 - Production line of fake cosmetic products in unhygienic conditions⁷⁵



Appendix 9 - Counterfeit manufacturing of Pfizer's products $^{76}\,$

http://www.dailymail.co.uk/news/article-3085665/Warning-fake-make-tainted-cyanide-dangerous-chemicals-Counterfeit-versions-leading-brands-cooked-criminals-squalid-underground-labs.html accessed 4 August 2018 ⁷⁵ see supra ⁷⁶ Pfizer, 'An Interactive Website Takes on the Fake Drug Trade' (Pfizer, 8 December 2016)





Appendix 10 - Falsified packaging of Paracetamol tablets⁷⁷



Appendix 11 - Comparison of an authentic Biogesic and a counterfeited one⁷⁸

https://www.pfizer.com/news/featured_stories/featured_stories_detail/an_interactive_website_takes_on_the_fak e_drug_trade ⁷⁷ Philippine news, 'Beware On Fake Version Of These Popular Medicine Brands Circulating In

Market' (Philippine News, 15 June 2017)

https://philnews.ph/2017/06/15/beware-fake-version-popular-medicine-brands-circulating-market/ accessed 4 August 2018 ⁷⁸ See supra



Appendix 12 - Example of anti-counterfeit campaign targeting developing countries⁷⁹



Appendix 13 - Counterfeit campaign to raise consumers' awareness



⁷⁹ See http://www.fakedrugskill.org/

Appendix 14 - Proposition of warning labels on drugs packaging⁸⁰



Patient Safety: How to stay safe in the doctor's office

- Signs of suspicious medication in the doctor's office.
 - Look for foreign writing
 - Ask to see bottle/bag/unit with lot number and write it down or take a photo



 Pay attention to new or unusual side effects or lack of therapeutic benefit and notify your physician/pharmacist.



Appendix 15 - Pfizer uses social media to promote anti-counterfeits campaign⁸¹

http://www.pharmafile.com/news/152591/digital-pharma-pfizer-anti-counterfeits-twitter-facebook accessed 28 August 2018



⁸⁰ Iracm, "Know your source": an awareness campaign to help us patients identify fake medicines ' (Iracm, 31 May 2016)

https://www.iracm.com/en/2016/05/know-your-source-an-awareness-campaign-to-help-us-patients-identifyfake-medicines/ accessed 4 August 2018 ⁸¹ Pharmafile, 'Digital Pharma: Social media boost for Pfizer anti-counterfeits campaign'(Pharmafile, 28th March

⁸¹ Pharmafile, 'Digital Pharma: Social media boost for Pfizer anti-counterfeits campaign'(Pharmafile, 28th March 2011)



Appendix 16 - EU common logo to redirect consumers towards legal Internet Pharmacies⁸²

⁸² Medicinesauthoritygovmt, 'Buying Medicinal Products Over The Internet And Internet Pharmacies' (Medicinesauthoritygovmt, unknown) <u>http://medicinesauthority.gov.mt/internetpharmacies</u> accessed 28 August 2018

