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PERSPECTIVE

In Pursuit of Robinson Crusoe:

Pharmaceutical Naming from the Lab to the Pharmacy

By Kristina Björnerstedt and Gunnel Nilsson

With more than ten years within pharmaceutical name creation, Kristina Björnerstedt, Managing director and naming consultant at Skriptor Zigila, and Gunnel Nilsson, Senior Trademark Attorney at IP Law firm Groth & Co, who has more than twenty years' experience from the pharmaceutical industry will share some of their insights and experiences in the everyday challenges of pharmaceutical naming. They have worked with more than 1000 naming projects for several of the largest pharmaceutical companies such as Pharmacia, Roche, Astra Zeneca, Boehringer Ingelheim, Actavis and Bayer.

Naming pharmaceuticals is a topic that has been thoroughly investigated and buzzed around, and where the world's expertise agrees on at least one thing. With today's increasingly dense jungle of brands, combined with the famously strict regulations of authorities such as the European Medicines Agency (EMA), the US Food and Drug Administration (FDA) and the WHO (World Health Organization), the naming of pharmaceuticals is a true challenge. A series of legal, regulatory, linguistic and market-oriented hurdles must be overcome, not to mention the limited number of letters in the alphabet. However, with sufficient persistence and experience, devising a new pharmaceutical name remains feasible.

When a pharmaceutical company develops a new medicine or new medical equipment, clinical studies are performed, lasting from a few weeks, up to a year or more depending on the issue studied. These studies take place in four different phases.

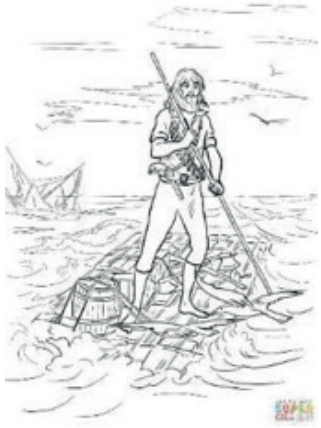
In phase one, generally speaking, 20 to 80 healthy individuals (usually male) will be used to assess the safety of the product. This assessment will look at the possible side effects and pharmacological properties of a given substance. In phase two, participants with the relevant illness or condition will be recruited. At this stage, you will get your first information of the effect of treatment on the relevant disease, and which kind of dose is optimal. In phase three, a large patient group will be studied (between 200 and 3000 individuals, or even more) or longer period of time, to confirm the effects and safety of a new treatment compared to the standard treatment. If this third phase is successful, you can apply to have the treatment approved.

Lastly, in the fourth and final phase, when the product has entered the market, major studies are undertaken to identify any unusual side effects and monitor the safety, efficacy and optimal use of the treatment.

The results from these clinical studies (phase 4 excluded) form an important part of the documentation required to obtain a drug approval for sale in Europe. Approval of new drugs is almost always based on a joint decision made by several or all EU Member States.

The completion of phase three is usually the point at which the naming process commences. A team of trademark attorneys, product managers, marketers and representatives from the research department, as well as experienced naming consultants, will join forces to christen the new product with its final trade name. In doing so, certain core questions must first be answered. What is the treatment area? What does the drug do? How is it taken (orally, by injection, etc.)? How does it differ from existing products?

Once these core aspects have been settled, the focus shifts to identifying relevant key words. What kind of qualities do you want the name to conjure up in the mind of the reader? Here, marketing departments may have a tendency to be somewhat optimistic, organizing ambitious workshops asking participants to characterize a new product as a 'James Bond', a 'Flash Gordon' or a 'Mother Teresa'. It remains to be seen whether these characters' qualities as smart, strong, or soothing would significantly assist in the creation of sustainable brand names that are capable of passing the above mentioned filtering and fulfil the regulatory and other requirements names of pharmaceuticals have to comply with. It may be that these rituals to some extent support the company's internal creative processes. However, the crucial challenge remains to be conquered - the applicable legal and regulatory requirements. In other words, the challenge is devising a name that is a 'survivor' - a 'Robinson Crusoe' for each and every drug assignment.



To highlight some of the difficulties with the name creation process, we can first point to some major changes that have been made in naming practices over the years, that have contributed to the transformation of 'name creation' into 'brand creation'.

The so-called 'Damitol pattern' (names with quasi-chemical connotations, usually a three-syllable word with a banal chemical/medical ending such as -al, -yl or -in) has been the one of the major naming methods in the pharmaceutical industry. Examples of 'Damitol pattern' names include well-known products such as Bricanyl, Aspirin, Toradol, Alvedon, to name a few.

Over time, the registration of names under trademark Class 5 - a very crowded class including pharmaceuticals - has become increasingly difficult due to similarity issues. Using the 'Damitol pattern' does not provide many original alternative brand names, and the similarity with already registered trademarks is of course inevitable. In order to avoid this risk new forms of name creation were necessary. An example of such, more creative name creation methods is in fact the well-known pharmaceutical Losec, which was considered a milestone when it was launched in 1988. The name was inspired by the term 'low secretion' (related to the function of the substance) and was not related to its generic substance, omeprazole.
Furthermore, the industry became more global and thus ideally, one product name should work in most market. Names of pharmaceuticals were gradually taking the form of 'brands'.

Another development in pharmaceutical name creation is that pharmaceutical authorities have raised the standards of naming pharmaceuticals in regards to names. For example, names should not be too similar, either in speech or in writing. They must not resemble the name of generic substances other than those included in the product, and they should not promise too much. An example of how these restrictions may influence the name creative process is illustrated in the case of the name 'Brilinta' as a name for a blood thinning drug, approximately ten years ago. This name was rejected by the EMA on the basis that, among other reasons, the name was too similar to the word 'brilliant'. Consequently, while 'Brilinta' was retained as the drug name in the United States, it was renamed as 'Brilique' in Europe.

When it comes to testing names prior to registration, several tests are performed by marketing authorization authorities, such as the handwriting tests. Both the European EMA and its US counterpart, the FDA, allow doctors to write hand-written prescriptions which in fact may be the source of confusion. A name that when handwritten is too similar to another pharmaceutical will thus not be registered.

The past ten years have given rise to, once again, a change of course in the pharmaceutical naming process. In particular, the market platforms of today seem even further removed from the traditional 'branding mindset'. There are several reasons for this. Firstly, according to many industry experts, the market for medicines targeting broad welfare diseases has declined. Secondly, research into diseases such as cancer result in medicines that target mostly specific types of cancer (such as pancreatic cancer, lung cancer and breast cancer) and fewer wide-ranging medicines.

Another challenge faced by the pharmaceutical industry is the so-called INN system. INN stands for 'International Non-Proprietary Names' and identifies pharmaceutical substances or active pharmaceutical ingredients. In the United States they are called USANs. Each INN is unique and globally approved, and are considered to be public property, and therefore not covered by the IP law. INN names are what is commonly referred to as generic names or 'generics'. The INN system as it exists today was initiated in 1950 by World Health Assembly Resolution WHA3.11 and came into force in 1953, when the first list of International Non-proprietary Names for Pharmaceutical Substances was published. The cumulative list of INNs now stands at some 7000 names, a number that is growing by 120-150 new names per year, referring to the WHO's website. The recommendation is to avoid INN strains in so-called stem words. They can be placed as prefix, infix or suffix. Many of these stems are distinct and easy to avoid, but the nightmare for a name creator is that there are also two- or three-letter variants that totally lack distinctiveness, such as '-al', '-ine' or the infix '-io-'. As a further example, 'Ni', 'Nic' and 'Nico' are indispensable aspects of the word 'Nicotine', and yet 'Ni' features on the list of elements to be avoided in naming. However, this is an issue that is constantly being scrutinised and discussed. At the annual international Pharmaceutical Trade Marks Group Conference in Dubrovnik 2018, several participants specifically addressed this issue with the WHO. In our opinion, WHO ensured that they will do everything possible to make it easier for the industry among other things, and that the requirements for the double-headed INN strains will eventually be reduced, eliminated or at least mitigated.

It is however important to remember that despite all the regulatory constraints there is still space for creativity. The wonder drug for treating male impotency Levitra is

named in honour of Adi Levit, Israel's leading litigator. He works for Unipharm and about once a year invalidates a block-buster drug in Israel. His impact in the industry is enormous. The word Ra means evil and so the name of the drug means 'Levit is evil'. The name giving in this case was the direct result of one of his courtroom battles.

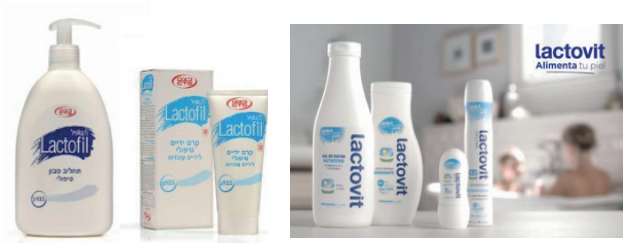
For more than 30 years, we have developed pharmaceutical names. One of our assignments in the 1990s, for pharmaceutical giant AstraZeneca, concerned a pharmaceutical product designed to lower cholesterol. The result was Crestor (rosuvastatin calcium), the most highly prescribed drug in the United States in 2014/2015. The inspiration for this name came from a person at AstraZeneca in Alderley, who expressed delight in the name Zestril (High Blood Pressure Medicine), based on the English word zest with the meaning of zeal, life appetite, spice. We decided to incorporate the word 'crest' - an English word meaning 'top'. From this, we developed the brand name Crestor.

A handwriting test mentioned above had an impact on the naming process of a drug produced by Takeda (known at the time as Nycomed). Under the framework of this project, we created the name Steovess for a drug developed for osteoporosis. In the United States, the FDA concluded that the name, when handwritten – could be confused with the name Atelvia, another anti-osteoporosis medicine. The letter A could in their view, be confused with any capital letter, and both names contained the letter 'v'. As a consequence, this drug had to be renamed 'Binosto' for the US market.

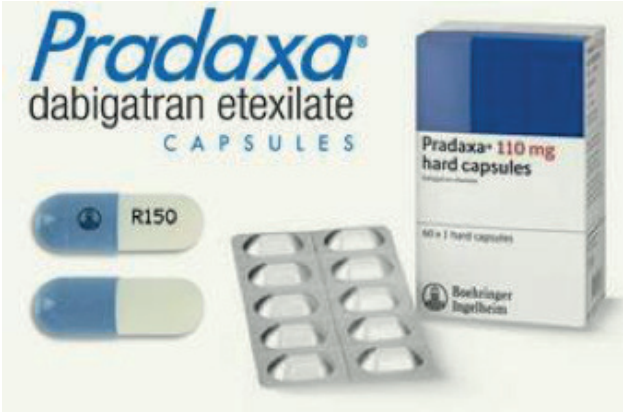
Another interesting name giving project concerned the registration of the pharmaceutical Lactovit in Israel. In this case, the pharmaceutical 'Lactovit', seeking registration as a body care product and Class 3 Trademark (soaps, gels, perfumery, essential oils, cosmetics, lotions for hair and skin care, creams for hair and skin care), was considered not confusingly similar to a prior registration for 'Lactofil', a Class 5 trademark (covering lotions, creams, mousses etc. for nourishment and cleaning of the skin). The adjudicating officer (see below) reasoned that consumers expect medicated products to be sold in pharmacies, whereas body care products are more likely to be sold in retail chains. As such, it was considered that consumers can easily distinguish between the marks 'Lactofil' and 'Lactovit', even if the goods covered by both marks are somewhat related.

As stated by Dr. Michael Factor (leading Israeli Patent and Trademark Attorney):

> *'Lacto' means milk. Like milk or* חלב *or* תחליב*. I cannot see any justification to allow a company to monopolize the prefix in Israel, despite it being in Latin and despite allegedly no-one using it previously as a prefix in a trademark. In Hebrew, the stress is on the final syllable not the first one as is the case in English. The similarities should be judged narrowly. The adjudicator is therefore correct and there is no real likelihood of confusion.'*



In 2001, we were engaged by Boehringer Ingelheim to develop a brand name for a new thrombin inhibitor anticoagulant preparation, with the generic name dabigatran. The individuals commissioning us desired a completely arbitrary name with up to three syllables. This was considered to be more distinctive and memorable, as well as being more well suited to meet the requirements of regulatory organisations such as the FDA and EMA. As many of the brand's competitors had named including the letter 'X' (Exanta, Arixtra, Clexane), this was also given as a possible direction. The result was PRADAXA, a purely invented name with no apparent reference to the disease, the generic name, or any dictionary word, but still distinctive and easy to pronounce in all major languages.



A relatively new and increasingly prevalent area within pharmaceutical naming is the borderland between medicine and information technology where, until recently, mainly descriptive product names or purely technical terms have been used to indicate the functionality of different products. We worked together with Context Vision, specialists in artificial intelligence and a world-leading supplier of software for the enhancement of medical images. We were assigned with developing a brand name for their new portfolio of digital decision support for pathologists that enable a faster diagnosis of eg. prostate cancer. INIFY™ was the name that was adopted chosen because it could bear a picture of both an 'overview' as well as that of an 'inner investigative details'. Of particular interest to us was that simple elements such as 'ini', corresponding to 'interior, inside' and 'ify' (which in English gives the feeling of a verb, such as in the words 'verify' and 'signify') were sufficient to meet the specific requirements set out in the client specification.

INIFY

Trademarks attract a great deal of attention and have become increasingly important in today's media noise. They also constitute a significant asset for a company, not only because they represent the products of a certain company, but also because they are a target of brand goodwill and are frequently used in market communications by pharmaceutical companies. The purpose of trademarks is to help consumers distinguish between products. However in the case of pharmaceutical products there are even other objectives that need to be taken into consideration, such as for instance patient safety. If a physician or a pharmacist confuses two medical products, such a mistake may expose the patient to great health risks.

On a personal note (KB), it is quite often a humbling experience to be part of the creative process regarding the development of names for medicines or equipment designed to minimize suffering.

In the complex world of pharmaceutical branding, where name creation is more difficult and challenging than ever, we find comfort in knowing we have done everything possible during the naming process down to every syllable, filter and legal detail to be able to create sustainable trademarks even in the future.

References: Kliniska studier Sverige, WHO, Peter Ekelund SkriptorZigila and Dr. Michael Factor, Israel Patent and Trademark Attorney.

Gunnel Nilsson

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Gunnel is a senior consultant, specializing in trademarks with particular focus on pharmaceuticals. She works with strategies in areas that include monitoring, name creation and branding, research, risk analyses and customs survey, and she manages IP portfolios. Gunnel has many years' experience of the special regulations that apply to IP in Life Science, primarily relating to pharmaceuticals in connection with agencies such as the FDA, EMA and Sweden's Medical Products Agency. Gunnel was also the Head of Trademarks at a global pharmaceuticals corporation.

Kristina Björnerstedt

Managing Partner at the international naming agency Skriptor Zigila.

Kristina is responsible for the Stockholm office, and is Chief Coordinator for the combined offices. She holds a degree in economics from Schartau Business Institute and has studied English and Czech, as well as International Relations at the University of Stockholm. She has also studied French, Italian, Russian and Latin. Kristina began her career at the Embassy of the Czech Republic in Stockholm, and holds a Certificate in Project Management. She grew up in a bilingual family and speaks fluent Czech.

With more than ten years at Skriptor, as a naming consultant and project manager, she has been working with many international and domestic clients such as Roche, Actavis, Axfood and Bayer.