Law Lore & Practice

PTMG Pharmaceutical Trade Marks Group

Dec 2023

Editorial: Plain speaking

The acquisition of language was a defining moment in human evolution. Knowledge, ideas and concepts could be communicated to other humans, and despite the existence of more than 7000 different languages spoken around the globe, and the emergence of AI generated language, this remains the primary function of words. As trade mark professionals, we have the unique privilege of 'playing' with words and language, thus acquiring a deeper understanding of linguistics. We are a profession steeped in the understanding that words have power – something we share with our friends in brand creation and marketing departments.

As much as language can be used to bring humans together, it can also be exploited to divide us. It is our responsibility to use it wisely to strive to communicate with compassion and to improve conditions for all our fellow humans. We must also be wary of language manipulated by those in power or those who control our modern tools of communication, so as to defend the 'Human Condition' as described by Hannah Arendt in her 1958 seminal work.

Saying good-bye to friends and colleagues in Athens with our Chairperson's call for peace at the Gala Dinner still ringing in our ears, we can be forgiven for feeling pessimistic as this year draws to a close. Communicating with our colleagues around the world so as to reach out to those who are suffering is yet another singular opportunity our profession offers. May we always strive to use our unique skill with language to build bridges where there are divides.

Please join me, and the PTMG Committee, in wishing peace and goodwill to all for 2024.

Vanessa

US Update

Jonathan S. Jennings Pattishall, McAuliffe, Newbury, Hilliard & Geraldson LLP

The Trademark, Trial and Appeal Board (TTAB) recently addressed the likelihood of confusion between a pharmaceutical trade mark and a similar one for cosmetics containing cannabidiol (CBD) https://ttabvue.uspto.gov/ttabvue/v?pno=91249673&pty=OPP&eno=55 The outcome illustrates the limits of establishing confusing similarity between marks for pharmaceuticals and CBD-infused products, respectively. With the continued popularity of CBD products, pharma companies must understand how to address them when their marks are implicated.

SAGELY NATURALS

Sagely Enterprises Inc. (Applicant) applied to register SAGELY and for skin creams, lotions, and related goods containing CBD in Class 3, and for analgesics, topical analgesic creams, medicated lotions, and related goods in Class 5. The applicant disclaimed the exclusive right to use 'naturals', apart from the marks as a whole.

Sage Therapeutics, Inc. (Opposer) opposed on likelihood of confusion grounds based on its prior rights in the registered mark SAGE THERAPEUTICS and design (one format shown below):

Sage Therapeutics

for a 'house mark for pharmaceutical preparations,' in Class 5. The exclusive right to use 'therapeutics' was disclaimed.

The case turned on the similarity of the goods after the Board found that the marks looked similar and had a similar connotation, as they both implied wisdom in some form. Applicant's non-CBD goods in Class 5 did not pose a difficult question for the Board. It noted that Opposer registered its goods in Class 5 as a house mark which under the USPTO trade mark rules 'identify the provider of a wide variety of goods or services.' The Board, relying on a dictionary definition, found that Applicant's analgesics, for example, were medicated and therefore fell under the rubric of pharmaceuticals in Class 5.

The outcome was different with regard to Applicant's class 3 goods. There the Board rejected Opposer's assertion that 'because CBD is classified as a drug, it is identical to a pharmaceutical preparation and ipso facto Applicant's cosmetics are related to Opposer's pharmaceuticals.' The Board noted that Class 3 is supposed to cover '[n]on-medicated cosmetics and toiletry preparations.' Further, in conformance with the trade mark rules and the Agriculture Improvement Act of 2018, Applicant's products only contained 'CBD derived from hemp and containing less than 0.3% THC.' This was a mandatory requirement to register CBD products as

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Words from the Chair

Dear All,

First of all, I would like to thank you all for your attendance at our Athens conference in October. Unforgettable moments were shared in a fantastic setting.

As mentioned in Athens these are uncertain times. In addition to the current geopolitical conflicts, it is important to acknowledge the financial crisis that has impacted various sectors, including the pharmaceutical industry. This crisis has brought forth profound changes, leading many companies to navigate through periods of questions and uncertainty.

Amidst these multifaceted challenges, we cannot overlook the plight of innocent civilians caught in the crossfire of geopolitical conflicts. As we brace ourselves for the cold temperatures in some conflict-ridden regions, our thoughts extend to those who not only endure the inclement weather conditions but also live in constant fear and uncertainty.
As intellectual property lawyers in the pharmaceutical field, our passion for serving patients and delivering groundbreaking medicines remains unwavering. It is through our professional dedication that we can strive to make a positive impact, not only within our industry but also in the world around us.

As we approach the end-of-year holidays, let us reflect on the resilience and adaptability that define us as professionals. May this season serve as a reminder of our collective strength and inspire us to navigate through uncertainties with hope and determination. By upholding our commitment to our mission, we can contribute to a future that brings peace to conflict-ridden regions and stability to our own industry.

Wishing you all the best for the upcoming end-of-year holidays, as we extend our thoughts and support to those facing hardships and uncertainty. May warmth, unity, and a renewed sense of hope prevail during this season and beyond.

Best regards,

Myrtha Hurtado Rivas

Members News

New Members

We are delighted to welcome the following new members to the Group:

Lisa Hart from Alcon, Vernier, Switzerland Lisa-1.hart@alcon.com

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US Update: continued

they fell within the definition of 'industrial hemp' and would not be considered a prohibited Controlled Substance.

The Board also rejected Opposer's argument that consumers understood the similarity between pharmaceutical preparations and products containing CBD. The published articles Opposer presented in support of its position, relating to the use of CBD in products, did not address customers' expectation of the performance of CBD as an ingredient in cosmetics. This suggests that consumer perception evidence might have altered the outcome of the case. Finally, the Board stated that precedent establishing that goods in Classes 3 and 5 are related did not control here, as Opposer still had the burden, which it did not meet, to establish actual relatedness of pharmaceuticals and CBD-infused cosmetics.

The Board sustained the opposition in part; rejecting Applicant's filing in Class 5, but not for Class 3. While Opposer presented evidence suggesting the potential medicinal benefit of CBD, it did not specifically relate to the expectations of consumers for cosmetics. Pharma companies seeking to successfully oppose the registration of marks for CBD-infused products will require more relevant evidence linking CBD products to pharmaceuticals.

Members News

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Moves and Mergers

Rembert Niebel has left Baker McKenzie and is now with SKW Schwarz in Frankfurt, Germany. Rembert can be contacted at r.niebel@skwschwarz.de

Jenevieve Maerker has left Foley Hoag LLP to join Finnegan Henderson Farabow Garrett & Dunner LLP in Boston Massachusetts, USA. Jenevieve can now be contacted at Jenevieve.maerker@finnegan.com

Rik Minoodt formerly with Darts-ip, is now with Fovea IP in Brussels, Belgium. Rik can be contacted at rik.minoodt@foveaip.com

Karol Gajek has left Sołtysiński Kawecki & Szlęzak to establish ViaMarca Kancelaria Adwokacko-Patentowa Karol Gajek in Dawidy Bankowe, Poland. Karol can be contacted at karol.gajek@viamarca.pl

Emily Ellis has moved from Ellis Terry to join Catalyst Intellectual Property in Auckland, New Zealand. Emily can be contacted at Emily.ellis@catalystip.co.nz

Aira Apivala has left Novartis International AG to join Société des Produits Nestlé S.A. in Vevey, Switzerland. Aira can be contacted at aira.apivala@nestle.com

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Inès Garlantezec has left Dennemeyer & Associates to join Marks & Clerk in Luxembourg. Inès can now be contacted at igarlantezec@marks-clerk.com

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Enrico Panza has left Ipan GmbH to join RightHub Ltd. in London, UK. Enrico can be contacted at epanza@righthub.com

Yassin Ghanim has left Wasaya Law & Legal Consultancy to join One World Intellectual Property LLC in Riyadh, Saudi Arabia. Yassin can be contacted at jghanim@oneworldip.com

Khushboo Butail Karol has left Krishna & Saurastri to join ANM Global Solitaires & Advocates in Mumbai, India. Khushboo can be contacted at Khushboo.butail@anmglobal.net

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Please remember to let us know of any changes to your contact details. You can notify me either via the PTMG website www.ptmg.org or directly to Lesley@ptmg.org or by writing to me at Tillingbourne House, 115 Gregories Road, Beaconsfield, Bucks, HP9 1HZ

Lesley Edwards
PTMG Secretary

Is Sylimarol different enough from silymarin to be a trade mark?

Beata Wojtkowska and Karolina Szafarowicz, Kulikowska & Kulikowski

In market practice it often happens that entities operating in the pharmaceutical sector select names for their products that are similar to the generic names of the substances contained in the preparations (names of active substances, international non-proprietary names - INNs). As a result, the question of how to assess the similarity of a trade mark to an international non-proprietary name is often raised in case law practice.

Valuable guidelines with regard to this problem appeared in the recent judgement of the Supreme Administrative Court (S.A.C.) of 6 July 2023. The S.A.C. assessed the correctness of dismissing the motion for cancellation against the trade mark SYLIMAROL with respect to goods inter alia in class 5 due to the lack of distinctive character because of its similarity to the name of the substance silymarin (in Polish: sylimaryna). In its judgment, the S.A.C. shared the position of the administrative bodies pronouncing earlier rulings in this case, i.e., the Polish Patent Office and the District Administrative Court, according to which cancellation of the mentioned trade mark was not justified.

The entity requesting cancellation argued that the mark directly referred to the name of the active substance on the INN list, and by the same described the type, intended use and composition of the product for which it was destined. The element 'sylimar' is derived from the active substance called silymarin/sylimaryna, which is used in medicine (Silymarin definition: [biochemistry] A mixture of flavonolignans extracted from milk thistle, Silybum marianum, used as a source of silibinin), and has 7 out of 9 letters in common with the name of the main ingredient. The addition of the suffix -ol, which is commonly used to form names of medicines and food supplements, does not make the sign distinctive, because there is still only an association with the name of the active substance.

The owner defended its trade mark by pointing out that a mere reference to the name of one of the ingredients of the active substance and an indirect association with it are not sufficient to consider the sign generic. The trade mark owner also pointed out that the INN list does not and has never contained the sign 'silymarin' or similar ones, and moreover, that the cancellation applicant itself had filed a trade mark application for SYLIMARON.

In the opinion of the Polish Patent Office, it was irrelevant for the assessment of distinctiveness whether silymarin was the active substance or only one of its components. The Office stated that the disputed trade mark was not identical or synonymous with the generic name sylimaryna or silymarin, and therefore the sign should be regarded as fanciful because, although it is capable of bringing silymarin/sylimaryna to mind, it was created only from a part of that name combined with the fanciful ending -ol. That the ending itself is popular does not change the assessment that the trade mark owner has created a new word, different from the name of the substance in the product. The Office also emphasised that the minimum criteria for distinctiveness are satisfied when the consumer perceives a difference between the described goods and the trade mark. Therefore, mere similarity to a generic name cannot be a basis for cancelling a right of protection.

In the course of considering the complaint filed against the Office's decision, the District Administrative Court agreed with the Office's argumentation that the disputed sign is not identical to the generic name, as it is not the name of the substance. On the contrary, it is a fanciful sign, a neologism created with a view to designate specific goods originating from a specific economic entity. The fact that silymarin is one of the ingredients in the product does not make the mark descriptive. The Court also noted that it is not unusual in the pharmaceutical industry to use as trade marks for medicinal products 'fanciful names formed from root words taken, inter alia, from the names of the basic chemical constituents of the product in question or the name of the disease for the remedy of which the product in question is intended, in combination with certain prefixes or a certain stereotypical ending', to which the suffix -ol also belongs. This leads to the market presence of many suggestive or allusive marks, which nevertheless have sufficient distinctive capability. If a sign is merely suggestive of certain characteristics of a product, this cannot lead to deeming it devoid of distinctiveness. The Court also disagreed with the claim that the disputed sign could be confused with the generic name of the substance, pointing out that in the case of generic names of active substances used in the production of pharmaceuticals, the arrangement of letters - their juxtaposition and sequence - is of fundamental importance and cannot escape the attention of the public.

The Supreme Administrative Court has dismissed the final appeal and upheld the judgment of the District Administrative Court. The ruling is in force.

The commented rulings in the case at hand support the previous line of decisions of the administrative courts in analogous cases.

In the case concerning the similarity of the sign CLOGREL to the INN clopidogrel, the District Administrative Court in Warsaw held in its judgment of 8 May 2009 that creative abbreviations of scientific names of chemical elements or fanciful signs formed from the root words of such names do not constitute generic designations; only scientific names of chemical elements in the strict sense can be deemed, in principle, to constitute generic designations with respect to pharmaceutical preparations. Consequently, the fact that CLOGREL refers to the generic name of the active substance clopidogrel, which is an ingredient of a pharmaceutical product, is not sufficient to regard the disputed sign as a generic name for that pharmaceutical product or as an indication merely informing about the characteristics of that product (although it does indirectly indicate certain characteristics of the product). It is sufficiently fanciful to have distinctive characteristics. Another case considered by the Supreme Administrative Court concerned the similarity between the sign GLAZIDE and the INN gliclazide – the difference consisting in the absence of the middle syllable -lic-. In its judgment of 16 December 2009, the S.A.C. ruled that the sign constituted a creative transformation of the name of the active substance and was in fact distinctive because it had a fanciful nature, did not constitute the generic name of the product nor did it directly communicate the product characteristics. Although it might evoke associations with the name of the active substance that was an ingredient of the medicinal product, this was not sufficient to regard the sign as a generic name of the product.

Summarizing, as it follows from the analysed case law, in order for a sign similar to an INN to obtain protection as a trade mark, the reference to the INN or to the name of the active substance must be fanciful. Creative modification of a scientific name must result in a designation that is capable of identifying a product on the market, that cannot be confused with the generic name of the substance and that allows the product in question to be identified on the market among goods of the same kind originating from different undertakings. Mere suggestion of certain product characteristics by evoking an association with the name of the substance used to produce it does not render the sign non-distinctive.

International Update

Egypt

PETOSEVIC

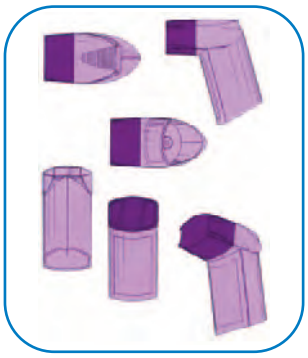
Egypt recently adopted Law 163 of 2023 which establishes the Egyptian Authority for Intellectual Property (EAIP) as the only state body authorized to grant and register all types of intellectual property rights.

Authority over IP matters, so far divided among multiple administrative bodies, will be integrated and centralized under EAIP, which will also assist judicial, administrative and police authorities in IPR matters. It is expected that EAIP will become operational by late 2024.

EUROPEAN UNION

Gill Dennis and Florian Traub, Pinsent Masons

Earlier this year, the EU General Court gave its decision in appeal proceedings concerning the validity of Glaxo's registration of a three dimensional EU trade mark for a purple inhaler as shown below (the Mark) in Case T-477/21, 24 May 2023. The Mark was registered under no. 2179562 in classes 5 and 10 and claimed the colours 'lilac (Pantone ref: 2645C) and deep purple (Pantone ref: 2617C) in or applied to the three-dimensional shape in the proportions shown in the illustration'.



Cipla Europe NV sought a declaration of invalidity of the Mark on the ground that it was devoid of distinctive character relying on Article 59(1)(a,) in conjunction with Article 7(1)(b), of Regulation 2017/1001.

The Cancellation Division of the EUIPO granted the declaration and this was upheld by the First Board of Appeal (BoA). Glaxo appealed to the General Court.

The General Court upheld the appeal. It held that the BoA had only examined the inherent distinctive character of each of the constituent individual elements of the Mark (namely the shape, colours and arrangement of the colours). However, it was apparent from case law that the assessment of the distinctive character of a compound trade mark must be based on the overall perception by the relevant public of that trade mark as a whole resulting from the particular combination of its elements. There was no presumption that elements individually devoid of distinctive character could not, on being combined, present such character.

The General Court also held that the BoA's reasoning had been contradictory. To reach its conclusion that the colours used for an asthma treating medicinal product were descriptive as referring to the product's active ingredients, purpose and characteristics, the BoA had relied on the evidence and discussions before the Cancellation Division and the General Court decision in Shade of the colour purple (T 187/19, 9 September 2020). However, the Cancellation Division had found that the evidence before it did not in fact sufficiently demonstrate that the colours indicated a characteristic of the goods. Further, the judgment in Shade of the colour purple concerned the assessment of the distinctive character of a colour as at 2015, which was fourteen years after the filing date of the Mark. The BoA had not explained why this decision was applicable to the Mark. Reliance on this judgment also ran counter to other findings in the BoA's decision that the pharmaceutical industry was developing constantly. Ten year periods were sufficiently long for the perception of goods to have changed according to new trends and product evolution and these factors gave rise to uncertainty which made it difficult to establish the validity of information concerning the distinctive or descriptive nature of colours back in time.

The failure to assess the Mark as a whole and the contradictory reasoning vitiated the BoA's decision, which the General Court annulled. In the meantime, the appeal has been reallocated to the Second Board of Appeal under no. R1835/2016-2 for reassessment.

This judgment confirms that distinctive character is determined by assessment of the mark as a whole, and that evidence that elements of the mark descriptively indicate characteristics of the goods must have current relevance in the sector concerned.

India

Ms. Alisha Rastogi, Chadha & Chadha

Background:

The Hon'ble High Court of Bombay delivered its verdict in the long-drawn conflict in Macleods Pharmaceuticals Limited v Union Of India And Others, between the pharmaceutical companies Macleods Pharmaceuticals Limited (hereon the Petitioner) and Sun Pharmaceuticals Ltd. (hereon the Respondent). The Petitioner filed the underlying Petition to challenge the Intellectual Property Appellate Board's (hereon the IPAB) order dated 30 December 2020, wherein the Rectification proceedings instituted by the Respondent against the Petitioner's trade mark OFLOMAC was decided in favour of the Respondent.

The Respondent's trade mark OFRAMAX has been registered with effect from 30 August 1989. However, the Petitioner's trade mark OFLOMAC was registered with effect from 28 January 1999. Subsequently, the Respondent initiated Rectification proceedings under section 57 of the Trade Marks Act, 1999 (hereon referred to as the Act) against the Petitioner's application on 29 October 2013. In response to the Rectification Proceedings, the IPAB decided in favour of the Respondent upholding that the Petitioner's mark OFLOMAC is of the nature to deceive the public or cause confusion with respect to the earlier mark of the Respondent as per the provisions of the Act.

It was the Petitioner's argument that the mark OFLOMAC was an amalgamation of the medication OFLOXACIN and the Petitioner's trade name MACLEODS. It also alleged that the mark was prior both in use and adoption whereas the Respondent had failed to prove its claim of use since 1991, a fact they claimed was overlooked by the IPAB.

On the other hand, the Respondent argued the validity of the IPAB's order in light of an earlier registration of its mark OFRAMAX which was granted registration back with effect from 1989.

Decision:

The Hon'ble Court deliberated upon the factors to be considered for equating deceptive similarity on the basis of the Supreme Court's decision in the landmark judgement in Cadila Healthcare Ltd v Cadila Pharmaceuticals Ltd. and other notable decisions and observed that: '…a confusion in terms of medicinal product or a pharmaceutical product may have disastrous effect on the health… The mere existence of the slightest probability of confusion in case of medicinal product marks, requires that the use of such mark be restrained… Factors such as phonetic similarity or similar pronunciation can cause a big confusion amongst the public. While arriving at a conclusion with respect to the similarity and confusion between medicinal products, the point of view of an ordinary common man of average intelligence should be considered instead of that of a specialised medicinal practitioner.'

Continued on next page

International Update continued

Accordingly, the Hon'ble Court held the Petitioner's mark to be confusingly similar to the Respondent's mark and upheld the decision of the IPAB.

The Hon'ble Court evidently acknowledged the requirement of a stricter application of factors establishing likelihood of confusion with respect to products of the medical/pharmaceutical category, in the interest of public wellbeing.

Kosovo

PETOSEVIC

The new Administrative Instruction (AI) on Trademark Registration Procedures No. 08/2023, which entered into force in Kosovo on 14 August 2023, addresses the most important changes brought by the new Law on Trade marks, in force as of July 2022.

Besides elaborating the novelties introduced by the new trade mark law and clarifying certain aspects of various procedures, the new AI also states that the Kosovo Intellectual Property Office (IPO) has accepted WIPO's Joint Recommendation Concerning Provisions on the Protection of Well-Known Marks meaning that the IPO can now refuse an application for a mark that is in conflict with a well-known international trade mark even if the latter is not registered in Kosovo.

Additionally, the Kosovo IPO has accepted the list of recommendations from the INTA Board Resolution on Bad Faith Trademark Applications and Registrations when assessing if an application was filed in bad faith.

Finally, according to the new AI, parties in an opposition procedure are now obliged to inform the IPO within 30 days from the date of the decision of the Complaint Committee of the Ministry of Industry, Entrepreneurship and Trade if a lawsuit against the decision has been filed with the competent Court. Otherwise, the IPO will consider the Complaint Committee's decision as final.

Qatar

PETOSEVIC

The Gulf Cooperation Council (GCC) Trade Mark Law and its Implementing Regulations entered into force in Qatar on 10 August 2023, replacing Qatar's previous Trade Mark Law No. 9 of 2002, with respect to trade marks, trade indications, trade names, geographical indications, and industrial designs. Qatar is the fifth GCC state after Bahrain, Kuwait, Oman, and Saudi Arabia to implement the law.

The GCC Trade Mark Law, unlike the GCC Patent Regulation, does not introduce a unified registration system, but is rather intended to align trade mark regulations and procedures across member states.

The most significant changes brought by the adoption of the GCC Trade Mark Law are the following:

- the examination process was shortened to a maximum of 90 days;
- the time to comply with examination conditions was reduced from six months to 90 days;
- the opposition period was reduced from four months to 60 days;
- the deadline to appeal an opposition decision before Court was reduced from 60 to 30 days;
- the law now provides more clarity on what constitutes a well-known trade mark;
- multi-class applications are now allowed; and
- it is emphasised that goods and services are not automatically deemed to be similar just because they are in the same class, or unrelated because they are in different classes.

In summary, Qatar's adoption of the GCC Trade Mark Law is a significant milestone for the harmonisation of IP regulations across the Gulf region. While there are positives, brand owners need to remain cognizant of the shortened formal deadlines and plan ahead when legalised documents are required.

Brand owners also need to be aware of the increased official fees for various services such as trade mark registrations, renewals and recordals, which entered into force in Qatar at the same time as the GCC Trade Mark Law.

Vietnam

Lin Lixia, mirandah

Vietnam Decree No. 65/2023/ND-CP (Decree 65) took effect on 23 August 2023. Decree 65 represents the latest state of IP rights establishment and enforcement in Vietnam. Decree 65 provides guidance on the implementation of the Intellectual Property Law 2022 (the IP Law), particularly in the realms of IP registration and enforcement.

In brief, Decree 65 refreshes the registration process for IP rights in Vietnam, clarifies the scope of actionable infringements, and enhances the customs handling process to enable stronger collaborations between rights holders and customs authorities.

IP Registration

New application and registration process

Decree 65 provides an all-new IP application and registration process:

- The application form, as well as renewal, amendment, recordal and licensing forms, have all been updated.
- Applicants can now make amendments and additions to the application form at any time before the Vietnam IP office (VNIPO) commences its review. This specifically includes amending the application mark to exclude elements that are not meant to be protected by the trade mark, so long as the distinctiveness of the trade mark is still retained.
- Trade mark applications can now be split based on the goods and services within the initial application.
- The VNIPO will now optionally issue electronic certificates so that post-registration processes can be streamlined.
- Sound marks can now be registered under Vietnam law. However, no further guidelines have been issued ever since Decree 65 came into effect.

International applications no longer subject to opposition procedures

Under Decree 65, there will no longer be any opposition procedures for international trade mark and industrial design applications.

Rather, third parties who wish to object to an international application can only submit written opinion letters to the VNIPO during the examination process. Even so, the VNIPO is not obliged to respond to, or even to take into account, such opinion letters.

It appears that Decree 65 is intended to expedite the examination process for such international applications. However, national applications will remain subject to undergo official opposition procedures.

IP Enforcement

Updated scope of infringement

In the realm of enforcement, Decree 65 also updates the law governing IP infringement in Vietnam. Under Decree 65, the following elements must all be present for an act to be considered infringing:

- The subject of the act is within the protected scope of IP under Vietnam law;

Continued on next page

International Update continued

- There is an infringement of the IP holder's rights;
- The person who committed the act is neither the IP holder, nor any person authorized by the IP holder.

The geographical scope of an infringement committed in Vietnam is also no longer confined to an act committed physically within Vietnam, but has been expanded to include websites that have a Vietnam domain name or are primarily written in Vietnamese, or are otherwise directed at Vietnamese consumers or users.

Updated definitions of loss

Under the updated definition of actual loss in Decree 65, the actual loss suffered by an aggrieved person, which arises from an infringement, arises when:

- The aggrieved person possesses, or is entitled to, certain material or immaterial benefits;
- The aggrieved person has the capacity to acquire the aforesaid benefits; and
- The infringement causes the aggrieved person to lose the aforesaid benefits, whether in part or entirely.

Additionally, Article 84 of Decree 65 specifically governs intangible losses, especially including damage to honour, dignity and reputation arising from IP infringement.

Customs handling of IPR-infringing goods

Decree 65 also marks a shift towards a more proactive approach in handling infringing goods. Unlike previous regulatory frameworks, which left the handling of infringing goods to the authorities' sole discretion, rights holders are now empowered to request the authorities to compel manufacturers of infringing goods to recall products.

Customs branches are now able to proactively suspend the import of suspected infringing goods up to 10 days from the date that it notifies the rights holder of the suspension. Additionally, customs branches are liable to compensate goods owners for any loss that the goods owners suffered if the customs branch incorrectly took suspension actions.

Protecting Brand Identity

Samta Mehra & Shrabani Rout, Remfry & Sagar, India

In a recent case of Glaxo Group Limited v Precado Healthcare Private Limited and Anr. CS(COMM)706/2023, the Delhi High Court once again discussed the aspect of intersection of intellectual property and public health. Glaxo Group Limited (plaintiff, hereinafter), a renowned global pharmaceutical company, filed a suit against Precado Healthcare (defendant, hereinafter) for imitating the packaging of its widely recognized brand AUGMENTIN.

The contention revolved around the defendant's use of green and white packaging for its product AMOXYDUO - 625, which closely resembled the packaging associated with the plaintiff's AUGMENTIN trade mark. Despite legal notices from the plaintiff, the defendant failed to respond, leading to the filing of the present suit.

The plaintiff's main concern was the potential confusion between AUGMENTIN and AMOXYDUO due to the similarity in packaging. They argued that this confusion could be particularly problematic in diverse markets, including both rural and urban areas, where AUGMENTIN is used. The similarity could lead to serious health risks, as consumers and even chemists might mistakenly interchange these products.

The Court examined the case in the context of established legal precedents, notably the Supreme Court judgement in Cadila Health Care v Cadila Pharmaceutical Ltd. In this context, the Court emphasized the supreme importance of avoiding confusion in pharmaceutical products, considering the severe implications for public health. It was held that a stricter approach is required in cases of medicinal preparations and products since any confusion between the respective medicinal products is likely to have a disastrous effect on public health.

Acknowledging the particular vulnerabilities in the pharmaceutical industry, such as the verbal request of drugs in hospitals, the involvement of patients who may be elderly or illiterate, and the vital nature of these products, the Court highlighted the dire consequences of any confusion in medicinal products. It noted that such confusion, especially with drugs that are often the last resort, can lead to dire outcomes.

In light of the same, the Delhi High Court held that the level of tolerance for confusion among consumers is very low in pharmaceutical products and cannot be easily condoned. Accordingly, the High Court granted an ex-parte injunction against the defendants, restraining them from using the contested packaging for AMOXYDUO. However, the injunction did not prohibit the use of the AMOXYDUO mark, provided the packaging was distinct from that of AUGMENTIN.

The Court's decision serves not only as a legal precedent but also as a cautionary tale for the pharmaceutical industry, emphasizing the need for stringent measures to protect public health at all costs.

Plaintff's packaging	Defendant's packaging
	
	
	
	

102nd Athens Conference Report: *PTMG at the Birthplace of Ethics – Time for some Principle Reflections on Pharmaceutical Trade Marks*

Hazel Tunney, Tomkins

Telling an Irish person that they have 'no word limit' for their report is a dangerous thing for an Editor to do. It's especially so when the report is on a conference so full of information, passion, and great experiences. The Editor shall have her work cut out. Athens was a truly remarkable conference, for many reasons.

The conference opened with a welcome reception on The Acropolis Terrace of the Intercontinental Athenaeum Hotel. On this balmy evening, we were treated to the view of the spectacularly lit Acropolis, upon which perches the Parthenon, dedicated to Athena, the Goddess of (inter alia) wisdom. The fact that she is also Goddess of warfare is, surely, neither here nor there…let's hope!

Myrtha Hurtado Rivas

Our Chairperson, Myrtha Hurtado Rivas opened the conference with a welcome in Greek, greeting the 390 attendees from 60 countries around the world. Highlighting to delegates that ideas for presentations are always welcome, we were introduced to our first speaker: Michael Himonas of SFEE – Hellenic Association of Pharma companies. Michael delivered a broad reaching talk, outlining the current state of the pharma industry in Greece – where is it now and where is it heading. In introducing his lecture by stating that he hates talking numbers with lawyers, Michael delivered a detailed and informative talk featuring many such numbers, which served to clearly illustrate Michael's points about how underfunding in Greece by government indicates that innovation is being hampered. In finishing his talk, Michael apologized once again for all the numbers, as we moved to the second talk of the morning – the Founders Lecture.

Michael Himonas

Our Chairperson explained the background of the Founders Lecture, for the benefit of all new attendees. Discussing how, since its founding in 1970, PTMG has held education as a key element of its purpose, Myrtha described how the Founders Lecture was introduced in 2012 to honour the Founders of PTMG, and, more particularly, Mr. Derek Rossitter. The intention of the Founders Lecture is to provide an opportunity for younger and in-house members the chance to present before a professional audience.

Andreas Jauch

Andreas Jauch of Merck KGaA delivered his talk, titled A Data Based Dynamic IP Portfolio during which we became acquainted with Leticia. Leticia is an innovative, business driven tool, based on mapping Trade Mark data with commercial data, intended to address many issues facing the management of large IP portfolios. IP being often viewed as a cost factor, rather than an investment, Leticia, Andreas discussed, seeks to marry commercial issues and inefficiencies, with legal risks, with a view to closing the disconnect between Trade Mark and business Teams. Internet search discloses that the translation for Leticia is 'joy'. Further searches disclose that 'Leticia does what her definition depicts: throughout her life, Leticia will be a bundle of happiness who makes people around her feel special and warm'. Given the clear success of, and warm reception for Leticia, it is clear this is a well-chosen name for an impressive solution to the problems outlined by Andreas.

Andreas's presentation, with useful examples of the type of real-time queries Leticia can address ('identify global non-use risks') had at its core how limited resources prevent Trade Mark teams from providing holistic and proactive, instead of only reactive, business support. Talking the delegates through the background, development, innovation and application of the Leticia system, it was a pleasure to hear Andreas state what many of us feel – in business, we can be somewhat underappreciated: lawyers can also be innovative! (We also don't necessarily hate numbers, either). Andreas's presentation sparked an interesting Q & A session.

Following the coffee break, the theme of both names and numbers continued into our third session. Delivered by Antoinette Lachat of Novartis (whose name, she related, means 'medicines of God') and Dr. Raffaella Balocco Matavelli of WHO, this talk which was flagged at the outset as 'not a polished one'.

Antoinette Lachat

Delegates would disagree with this statement, and the talk was filled with detailed knowledge and fascinating insights. A lively, engaging and collaborative approach from the speakers led to the 80-minute session entitled All the things you wanted to know about INNs passing significantly more quickly than one might expect. Antoinette and Raffaella discussed how INNs and Trade Marks are 'allies and not aliens', and the various ways in which their allied nature can be improved and increased. Noting that 'without a name you cannot do anything', this session discussed how creating an INN is a science while creating a Trade Mark is art. To illustrate the scientific aspect of the talk, and flagging that she 'hates numbers', Raffaella disclosed to us numerous interesting and informative slides illustrating the numbers of existing INNs, and more particularly, their spiraling rate of increase. Using, in particular, INNs with –mab stems, she demonstrated the surging monoclonal antibody INN applications

Dr. Raffaella Balocco Matavelli

Continued on next page

Conference Report: continued

being received, necessitating the creation of sub-stems/new stems in order to deal with their influx. The exchanges about the complexity of INNs and how they interface with Trade Marks 'in the wild', disclosed some personal favorite INNs (checks notes):- Varnimcabtagene autoleucel, anbalcabtagene autoleucel, and itezocaptagen autoleucel….

After lunch, Hasan Khan of United Trade Mark and Patent Services took the stage for an Update on the Court/Regulatory system in Pakistan. The talk started with an introduction to Pakistan, and its pharmaceutical industry, which interestingly, consists of largely local companies; at odds with the Greek situation discussed earlier in the morning. Our speaker discussed how there are potential issues with International Registrations with certain designation dates that may risk being unaccepted by the Courts, after the new Act that came into effect in August 2023. An interesting and illustrative guide with respect to confusing similarity between trade marks, particularly those written in Urdu ('it's all Greek to me') drew chuckles from the delegates. It was reinforced that registration in the local language should be obtained. A brief Q and A session followed, where discussions focused on how the threshold for likelihood of confusion in Pakistan is lower, because of the nature of pharmaceutical products, and their implications with respect to public health and safety.

Hasan Khan

Alexios Skarlatos

Alexios Skarlatos of NRG, EMA next took the floor with his talk on An update on the new NRG Guidelines. Alexios explained at the outset that the main focus of the NRG and the EMA is patient safety, and that this is the only basis upon which refusals to register names are issued. Alexios highlighted the increasing number of names being presented which consist of a string of consonants and vowels, which can present serious issues, particularly if unpronounceable. This is particularly true in the context of emergencies, and when a drug needs to be spoken; pronunciation aspects (in all languages of the EU) are important. To illustrate same, Alexios pronounced for us three names and asked us to guess how they were spelt. This reporters' guesses were: 1. ENTRILIO, 2. AKAYEPHIL and 3. MARYNTRAYZE. Oh dear….

Alexios discussed how certain trade marks need to fit on small containers, and how very long names can create clear issues: the practical implications of names and name changes all have to be considered. Clearly, when it comes to pharmaceutical trade marks, the choice of a name may not be simply an art; given how pharma trade mark choices dovetail with both INNs and the EMA it arguably must become something of a science, given the interfaces and complex interactions involved.

Towards the end of the talk and after displaying the various, many incorrect guesses as to the trade marks earlier mentioned in his speech, the correct spellings were revealed by Alexios to be: –

1. MTRYYLIO
2. ACKEYFLN
3. MAUNGREEIS

Wow. All Greek to me, indeed….

Stephanie Gumm

Next up was Stephanie Gumm of Faegre Drinker, Biddle & Reath speaking on AI and its impact on IP in the Pharma industry. Stephanie began her talk with an introduction about the evolution of AI and a general discussion about its clear and immediate adoption within the workplace at large. A show of hands illustrated that a significant number of delegates were already using AI on some level within their own practice. The rapid integration of AI was highlighted by the revelation that there were 1 million users of ChatGPT just 5 days after its launch. Stephanie demonstrated to the delegates how ChatGPT, using certain criteria which she inputted, generated a song about a stay in Athens in October, in the style of Nina Simone ('…a song about Athens; a memory'). The discussion moved on to discuss how the basic framework already in place in trade mark and copyright law protects certain aspects of how content creators and trade mark holders are protected by AI generated works. Discussing same, she underlined the importance of in-depth and detailed records about which works are generated by AI, which were generated by human assets; and the interaction between the two. Discussing certain aspects of AI related matters before the Courts as stated by Stephanie, 2023 was indeed the year of AI lawsuits. The direct implications of AI in the pharmaceutical trade marks field were then discussed, and most interesting, it is the interaction with both brand choice, and marketing/consumer engagement, which is where AI could 'shine' for pharma. Of particular potential interest was the use of AI in trade mark enforcement, and in particular for the identification and investigation of issues, and the issuance of takedown notices. It is clear not only per se, but on the basis of this presentation that AI will absolutely change how we practice trade mark law, and the key is to harness its power to complement current practices.

In closing the session, our Chairperson expressed a heartfelt recommendation / warning to wear flat shoes to our culture evening taking place at Thissio View. Reached by cobble locked paveway, delegates were treated to a most sensational view of The Acropolis, while seated under a canopy of fairy lit olive trees. A wonderful meal of Greek food was enjoyed, accompanied by local wine and music, and interactive Greek dancing. It may or may not be true that afterwards a contingent of attendees managed to locate firstly, the city's only Death metal/Goth bar, and subsequently (and very quickly afterwards) the city's finest karaoke bar. This reporter couldn't possibly comment…

Day 3's sessions were opened by our Chairperson, who introduced PTMG's only ice swimming, cheerleading, Finnish attorney (We are open to correction as to whether she is, in fact, PTMG's only ice swimming, cheerleading, Finnish attorney). Taru Kallio-Nyholm, of Orion Corporation delivered a deeply passionate, informative talk about the selection and creation of pharma brands. Taru encouraged attendees to remember the role of the brand, that it is an empty vessel, which is filled with meaning, particularly in these post– COVID days. Taru left delegates with plenty to reflect upon, asking whether trade mark law is serving the brand owners, and encouraging us to remember the role of the brand…

Taru Kallio-Nyholm

Continued on next page

Conference Report: continued

Taru's talk linked with the talk immediately following particularly well, as we moved into a discussion about the birth of a new world-wide corporate brand – HALEON. This talk, delivered by Sophie Bodet of Haleon and Sue Daun of Interbrand, was, we were assured 'not a legal talk' and took the approach of a completely interactive discussion between both presenters and the audience. The discussion revolved around how collaboration in brand creation is key, especially in finding a name which recognises consumer concerns. It was further discussed how brand choices are more than trade marks, and how that must also include social media, company names, domain names, but interestingly, stock market tickers. In choosing the name (being a merger of the elements Hale from an old advertisement for Beecham's powders, and Leon for lion or courage), a name with gravitas, yet one which was still fresh, had been found.

Sophie Bodet

Sue Daun

Internal transliterations of HALEON were arranged, to ensure that the meaning and story behind the new brand were captured. What followed then was more than a thousand applications and registrations for the mark. It was clear how, for HALEON, the name and the story of the brand are deeply intertwined. The session triggered a large number of questions, with a welcome coffee break finishing off an insightful morning, filled with passion and purpose.

We moved swiftly into the International Case Roundup, presented by Evan Fultz of Womble Bond Dickinson. Our speaker, in order to keep us on our toes, peppered his talk with pop quiz questions to check that we were paying attention. Evan started with the Glaxo v Cipla Europe GC (inhalers in a lilac/dark purple colourway) observing that the GC found the Board erred by failing to consider the mark as a whole, and provided contradictory reasoning as to the alleged non-distinctiveness as of the filing date. As we moved on to the (UK) case of Lidl v Tesco, we learned that cricket does not feature in the summer Olympics, and that the most popular sport in the EU that does feature is football (soccer, for US PTMG friends). The main observations on the Lidl v Tesco case are that use of a registered logo may withstand a non-use challenge - even if only used with incorporated text; bad faith may still be found as of time of filing; and that retaining records of intent to use as of filing date is advisable!

Evan Fultz

Learning that the second most popular sport in the UK, that also features in the summer Olympics is, somewhat surprisingly, boxing, we then moved to the US Case of Spireon v Flex where it was held that absent proof of non-use of similar marks, use will be assumed (and that the importance of similar third-party marks should not be discounted!)

Evan discussed Bertini v Apple and the issue of 'tracking' (can be done; but there is a high standard requiring equivalent marks and substantially identical goods/services – and how same must be established for each), whereupon we learned that the most popular sport in the US also featuring in the summer Olympics is basketball. (We later learned that the most popular sport in China featuring in the Olympics is likewise basketball). Moving to discuss how in two Indian cases (Mankind Pharma v Novakind Bio Sciences; Glaxosmithkline v Horizon) an increased degree of care is applied to pharma trade marks, given the market realities in that jurisdiction, we found out that the most popular Indian sport in the summer Olympics was badminton. After discussing Canadian Case law in comparative advertising (Energizer v Duracell), it was disclosed that Canada's favourite sport of the summer Olympics was football.

The last talk of the morning was delivered by Anthony Rodiadis, of EU Commission DG Health. Anthony delivered his detailed talk about the incoming new Regulation and Directive, intended to try and reduce the regulatory burden, and to drive innovation in the pharma sector. The interesting, technical talk delivered detailed information, sparking discussions about pharma availability and shortage issues. It was discussed how the idea behind the new regulatory framework is to make it more streamlined and agile, and also to particularly combat the issue of antimicrobials and the developing AMR issue (and the market failure for this market sector) as well as issues pertaining to medicines for rare diseases. This also gave rise to a number of questions surrounding parallel trade, and meeting the demands for certain pharmaceuticals.

Anthony Rodiadis

Wiebke Baars

After a pleasant lunch break, we moved to the well-attended session delivered by Wiebke Baars and Alison Dennis from Taylor Wessing, on the subject of green washing. A very informative, interactive and accessible session discussed what a complex area of emerging law it is, and that there are clear issues for the pharmaceutical industry arising. The talk provided a joint perspective from both the UK and Germany and centred on a number of illustrative, interactive case studies, demonstrating the play between legal and marketing teams when it comes to making such 'green claims'. While it's clear that 'net zero' and related terms are 'cool', the exploration by the speakers into the regulatory aspects of such claims whether made by marks, statements or logos illustrated how easy it can be for such claims to become quickly unavailable, inadvisable, or deeply unwise.

Alison Dennis

Continued on next page

Conference Report: continued

Anke Nordemann Schiffel

Anke Nordemann Schiffel from Nordemann Czychowski & Partner next took the stage, delivering a talk about copyright and healthcare, and the issues arising in connection therewith. Discussing the essentials of copyright, including AI copyright issues, an excellent visual overview of the types of works in which copyright protection might be enjoyed was then provided. The presentation discussed the individual copyrights arising, and their interplay within the various media available to pharma, and in particular those appearing on websites and social media. From this talk the delegates were advised not to underestimate copyright protection, and to be aware of rights one might have to acquire in copyright, especially in a global context.

We moved next to the final talk, delivered by Bruce Longbottom of Lilly and Megan Bannigan of Debevoise & Plimpton, who thanked the Chair 'a lot' for being 'awarded' said slot. Ensuring that the delegates remained awake and engaged, Bruce was accompanied by a 'Bad Spaniels' squeaking dog toy, much to everyone's mirth. Bruce, as in-house Counsel discussed the two recent Supreme Court decision's relating to 'Bad Spaniels', and in particular, how the First Amendment and trade mark law interact in connection with this matter. Speaking from his own experiences, Bruce discussed how parody and pharma can have deep reaching consequences, and how it is important to bear in mind the public perception of pharmaceutical companies. Basically, not all parodies are the same… Outside Counsel – Megan - then provided her perspective, illustrating once again how the interactive approach to the delivery of certain talks can bring an extra level of engagement with the audience, by illustrating how they may apply in real life situations. The discussion then moved on to Abitron Austria v Hetronic Germany case and the extraterritorial application of the Lanham Act. The takeaways from this talk were broadly the same from both an in-house and external perspective, and included: make sure to register abroad, to have application(s) in place to record the marks with Customs, and to monitor infringing activities. The upcoming case TRUMP TOO SMALL was flagged as one worth watching, as well as the WAVY BABY case. The final question arising - for which the prize of the 'Bad Spaniels' dog toy was awarded - addressed the key issue of whether and to what extent canines are in detailed legal surveys. Answer: They are not.

Bruce Longbottom

Megan Bannigan

Concluding the educational part of the sessions, our speakers were thanked by the Chairperson, before a final tea break, and preparations for our Gala Dinner and Dance at Zappeion Megaron. The Zappeion was the very first building to be erected for the revival of the modern Olympic Games. It was used during the 1986 Summer Olympics as the main fencing hall, and, in more recent times, as the location for the signing of documents formalising Greece's accession to the European Community. A glamorous venue with traditions steeped in the law, Europe, and sabre rattling? A more appropriate venue for the PTMG finale one could not imagine. To deep approval, our Chairperson announced the location the 2024 Autumn meeting – Malta! After a wonderful meal, music soon started, and in many years of attending, this reporter cannot remember a time when the dance floor hit so hard, so quickly, or so enthusiastically. Our DJ – highly receptive to music suggestions - was begged several times to play just one more tune. It's difficult to pinpoint when the music ended exactly but it was, one suspects, to the relief of our excellent PTMG staff, and their assistants…It is unclear whether a karaoke bar was visited or not, but one suspects Athens had been graced with the performance skill of PTMG delegates enough for one weekend already…

While education forms one of the keystones of PTMG, the sense of deep and broad friendship and that of community, which runs through its heart, must be acknowledged as another. Perhaps that is what makes PTMG such a special experience. That, and perhaps karaoke?

See you in Valencia, PTMG friends.

The Chairperson presenting long serving Committee member, Joëlle Sanit Hugot from Sanofi, with a retirement gift at the Gala Dinner.

103rd PTMG Conference

Valencia
25-26 March 2024

Booking opens in January

Social media and influencer marketing in the healthcare industry: Opportunities and limitations for the German market

Margret Knitter (Attorney at Law) and Dr Oliver Stöckel (Attorney at Law), SKW Schwarz, Germany

Social media marketing and collaboration with influencers are now part of the standard advertising repertoire for many companies. The healthcare industry is also looking for ways to effectively promote its products and services on social media. However, there are numerous restrictions to be observed, especially in Germany. What options are there for advertising with health influencers? How can legally compliant influencer marketing be carried out in the healthcare & life sciences sector?

A. General principles of cooperation with influencers

I. Principles of cooperation

Firstly, the basics of any collaboration with influencers need to be defined for each specific campaign: What content should be communicated on which platforms? Which influencer or group of people can convey the message most credibly - professional influencers, patients, medically trained staff or your own employees?

Even if the social media presence should appear spontaneous and approachable, the specific framework for the collaboration requires a detailed contractual basis, especially in the healthcare sector. In particular, the platforms, the number and scope of posts, the time period, the hashtags to be used, content to be created, unauthorised content and publication dates should be precisely defined. If influencers are given a free hand in the design of the posts to ensure authenticity, the company should retain approval rights before publication in the healthcare sector in order to protect itself against legal violations.

Legal aspects must also be taken into account. For example, the rights of use to the content created should be transferred from the influencer to the advertising company and explicit requirements should be included in the contract to ensure the influencer's compliance with labelling obligations.

II. Liability

The legal structure of the social media campaign is of particular importance. This is because the company behind the sponsorship may be liable for influencer content.

If the influencer violates legal requirements, such as labelling obligations under unfair competition law, or intellectual property rights, the company itself is liable under the Unfair Competition Act or intellectual property laws for injunctive relief and removal.

B. Special requirements of influencer marketing in the healthcare & life sciences sector

I. Healthcare advertising law and health influencer marketing

The Healthcare Advertising Act (Heilmittelwerbegesetz - HWG) must be observed for social media posts. However, it only applies to product-related advertising, and not to general company related advertising or PR. General information on diseases and their treatments (e.g. disease awareness campaigns) without a specific product reference are not covered by the HWG. However, if the content makes one or more products identifiable and is suitable to promote such products, this is sufficient to constitute product related advertising.

If the HWG is applicable, numerous limitations must be observed:

- Prescription medicines may not be advertised at all in generally accessible social media, including by influencers. For this product group, influencer marketing is only allowed on special platforms that are only accessible to healthcare professionals (e.g. via DocCheck).
- Non prescription medicines, medical devices, treatments and procedures can generally be advertised via health influencers. However, numerous content related prohibitions and restrictions must be observed.
- The so called 'principle of strictness' applies to all forms of health advertising: all statements made by health influencers must be clear, unambiguous and scientifically proven. Due to these strict requirements, the usual informal and abbreviated form of presentation in influencer posts, shares and comments can very quickly lead to a violation of the prohibition of misleading statements.

In practice, violations of the HWG often occur, especially in connection with the principle of strictness, for example, postings with recommendations from the medical profession or celebrities and the reproduction of medical histories ('patient journeys'). Testimonials that are abusive, repulsive or misleading are prohibited. However, lighter restrictions apply to medical devices - many of the prohibitions that apply to pharmaceutical products do not apply to the advertising of medical devices.

Finally, at least one clearly visible hyperlink that can be clicked without scrolling must be made to the mandatory product information if the content of a post is product related pharmaceutical advertising.

II. Prohibitions of donations and related compliance issues

Influencer marketing in the healthcare sector is also made more difficult by the numerous industry specific prohibitions of donations. A clearly regulated contractual relationship with an appropriate ratio of service (influencer activity) and consideration (remuneration, free services, other benefits) in compliance with the four basic principles of healthcare compliance (separation principle; transparency principle; equivalence principle; and documentation principle) is essential.

III. Special limitations for doctors as influencers

In the case of doctors as influencers, further restrictions are imposed by medical professional law. Product-related advertising is generally prohibited for doctors: firstly, the object of a contractual relationship with doctors may only be a medical, professional or scientific activity, and not a commercial or advertising one. Secondly, doctors are not allowed to advertise specific products or treatments.

As a consequence, doctors may only be influencers in the area of medical and scientific information.

Continued on next page

Social media and influencer marketing: continued

IV. Further issues

Depending on the structure of the collaboration with health influencers, there are other legal aspects to consider e.g. Code of Conduct requirements for social media marketing with patient organisations.

Health influencer marketing can also affect pharmacovigilance and drug safety, e.g. when social media users report side effects or post drug uses that constitute off-label use, contain medically incorrect statements or lead to dangerous self-diagnosis.

C. Conclusion and practical recommendation

Health influencer marketing offers great opportunities to reach a broad audience on health related topics. However, it also encompasses legal challenges. Due to numerous pitfalls and the frequent threat of legal violations, health influencer marketing requires precise planning, a clearly defined approach and, above all, a thorough legal review and structuring. It is not enough to have a general knowledge of influencer marketing - the considerable overlap between the specialized subject matter of healthcare advertising law and compliance requires in depth knowledge and experience in both areas of law. Many statutory limitations apply and mitigation of risks to influencers by contract is only possible to a limited extent. Internal training, easy to understand guidelines and clear instructions for at least the areas of marketing, sales, compliance, regulatory, customer/patient relations and legal are essential.

Cross-border trade mark agreements in the pharmaceutical world: A case study of Ekuberg Pharma's licensing and distribution strategy in Asia

Giulia Della Nina (Counsel), Abion, Sweden

In the ever-evolving landscape of pharmaceutical collaborations, a recent deal concluded by Ekuberg Pharma S.r.l sheds light on the importance of meticulous contractual negotiations and regulatory considerations when venturing into cross-border agreements.

The deal centered around trade mark licensing and distribution agreements and underscores the need for companies to adopt a strategic approach when dealing with these matters, especially in countries with particular regulatory frameworks such as China, Hong Kong, Macao, and Taiwan.

Ekuberg Pharma, an esteemed Italian pharmaceutical and dietary supplement manufacturer, had to quickly finalize an agreement to regulate the licensing of the other party's trade mark within the realm of the launch of new products on the Asian market. In particular, the product packaging displayed both companies' trade marks, calling for a careful due diligence and management of the rights involved.

A trade mark licensing agreement played a key role, delineating the terms and conditions governing the relationship between the involved parties, namely, Ekuberg Pharma on the one side and the distributor and trade mark rights owner (and its its subsidiary companies) on the other side.

The owner of the Chinese trade mark granted Ekuberg Pharma a non-exclusive, non-transferable license for the use of the trade mark concerning specific products in both the Chinese Mainland and Italy.

The agreement also granted Ekuberg Pharma licenses for Hong Kong, Macau, and Taiwan, with detailed provisions outlined in a separate contract.

However, the deal was not just about contract negotiation and finalisation. It also involved manoeuvring through the complex regulations applicable in the Chinese market. Ekuberg Pharma sought to successfully launch the new products, navigating through the challenges posed by the stringent regulations governing pharmaceutical products.

In response to potential advertising restrictions, Ekuberg set forth a dual trade mark strategy and actively pursued preferential treatment from Chinese authorities in the event of a product removal scenario.

The case revealed uncertainties about the ownership of the various trade mark applications and registrations belonging to the other side's trade mark portfolio. In fact, by carrying out in-depth searches, the scenario revealed different owners of the various trade marks in the countries involved and the absence of trade mark protection in certain jurisdictions.

This highlighted the pivotal role of clear communication and meticulous documentation to avert potential disputes and ensure the seamless continuation of the business relationship.

In a broader context, Ekuberg Pharma's experience underscores the indispensable role of thorough due diligence, unambiguous communication, and comprehensive contractual agreements with regard to the complex field of trade mark management in the pharmaceutical world.

As Ekuberg Pharma continues to pilot the complexities of cross-border collaborations, its critical elements of success include understanding regional regulations, securing unambiguous trade mark ownership, and proactively foreseeing potential disputes. In an industry where regulatory landscapes are diverse and continually evolving, meticulous planning and strategic foresight become imperative for pharmaceutical companies to thrive in international markets.

The deal serves as a compelling illustration of the delicate balance required to negotiate agreements that transcend geographical boundaries, and emphasizes the need for adaptability, clarity, and foresight in the ever-dynamic landscape of international business.

PROFILE: Antoinette Lachat

Straight after my exams, I started with Ciba-Geigy to become a trade mark specialist. I was responsible for the Agro portfolio and - after the Merger with Sandoz - for the Agro team until the Syngenta spin-off. I then took over the Ciba-Vision and Nutrition portfolios and team until I was requested to lead one of the 2 pharma trade mark teams, when regulatory name rejections hit the company. For the past 15 years, I focussed on the Immunology portfolio, INN projects and country responsibility for China. In parallel to the portfolio work, I lead numerous IT, quality, policy and SOP projects.

Where were you brought up and educated?

In Basel, Switzerland, with a MA in English & in German Philology and a Batchelor in Educational Psychology.

How did you become involved in trade marks?

We evaluated product naming concepts in one of my linguistic courses at University. When Ciba-Geigy posted a job opening in the trade mark department, I felt I had some idea of what that job might look like, applied for it and was lucky to get it.

What would you have done if you hadn't become involved in intellectual property?

Any role involving interactions with human beings around the world would have been appealing to me

Which three words would you use to describe yourself?

Curious, spontaneous, solution-focussed.

Complete the sentence: If I have time to myself ...I enjoy connecting with people who I feel close to.

Complete the sentence: I'm no good at ... giving short answers.

What's the best thing about your job?

Its constant evolution – it is human intuition to use identifiers in our daily interaction, to create new ones or develop our private codes. The job will never get boring as innovation, new technologies, human beings and geopolitics keep changing our world and result in new needs for additional, different identifiers. So, the depth and breadth of an inhouse counsel's role is fantastic, both on subject matter topics as well as on strategic or project management levels. Combined with the international relationships we can build with business partners, with third party representatives (aka 'competitors'), or providers - I still consider this job a dream job.

What do you wish more people would take notice of?

That we really have to respect this one world where we are currently living as guests.

What would be your ideal night out?

A modern ballet, a cabaret performance, or a games evening - all in good company.

What is your philosophy in a nutshell?

Nothing is ever so bad it is not good for something else.

Who was your mentor and / or role model?

The late Werner Haring. If I had not had the privilege to have such an inspiring boss during the first third of my business life, I would not have grown to become the versatile professional that I am today.

What is your weakness?

I am not good at crafting anything with my own two hands.

Which book changed you?

Thomas A. Harris – 'I'm ok, you're ok'

Which music recording would you take with you to a desert island

My long playlist consisting of Runrig, Simply Red, Supertramp and Queen.

What music is in the CD player in your car / what is your iPod set to at the moment? ?

KA (Cirque du Soleil).

How do you relax?

I enjoy going outside for a walk in nature.

What is your favourite food dish?

Scaloppine al Limone with a risotto.

Which is your favourite restaurant? ?

I am blessed to have excellent cooks in the family :-).

What is your favourite drink?

Sparkling water.

Which word or sentence do you most often say?

Life is too short.

What is your most treasured possession?

My close relationships are what I treasure most; I do not consider them a possession, though.

Do you have any unfulfilled ambitions?

I would love to be able to play diabolo or juggle several balls in real life.

What is your favourite item of jewellery?

My wedding ring.

Where do you see yourself in 10 years' time?

I hope for a healthy and fulfilling retirement with sufficient time for family and friends – curious how it will evolve.

What is your favourite building / piece of architecture and why?

Sydney Opera House, because of its spectacular exterior design that not only gives a home to outstanding stage performances, but also has become a stage of its own thanks to the Lighting the Sails creations.

What's the best invention ever?

Fresh water supply.

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