

Law Lore & Practice



Pharmaceutical
Trade Marks Group

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Editorial: We are what we eat....

As Christmas approaches and thoughts turn to menus, one wonders whether the media actually do bombard us with more food related stories or whether our senses are merely more tuned in to this topic at this time of year. The outbreak of avian influenza on a duck farm in Yorkshire, UK last month brought

bio security back on the radar whilst the Archbishop of Canterbury's recent comments in a UK Sunday newspaper again raised the profile of the issue of food poverty.

You could be forgiven for thinking that living in France gives you a warped view of the importance of eating in the daily routine. After all, in this country you live to eat rather than the other way round. A clear indication of this is the so-called "Commission Menu" which takes place twice a term in every secondary school to determine what will be served at the school canteen. Parents, students and school management staff as well as the school chef and his purchasing team discuss, share feedback and plan upcoming menus. School dinners here are a four course affair with very stringent criteria to ensure a balanced, low salt and sugar diet is offered to teenagers. A far cry from the tuck shop ! However, the net result of these regulations is massive waste since a lot of what is served doesn't

look like food from home.

There is definitely a revival in the developed world for locally grown and sourced food supplies. Vegetables that had gone out of fashion are back with a vengeance and allotments have become a very trendy way to socialize. Major supermarket chains are having to re-think their global business models and people are voting with their shopping baskets.

What we eat, how we eat and where the food comes from concerns us all wherever we live. Government leaders met in November this year at the second International Conference on nutrition and the World Health Organisation will dedicate its World Health Day on April 7, 2015 to food safety. WHO's Director-General, Margaret Chan's comments in the Lancet on the topic underlined the intrinsic link between what we swallow and our on-going health. Hopefully the next generation will be more attuned to sustainable food supplies and thus naturally improve their long term health prospects.

What we can be sure of is that the food served at the PTMG Conference in Venice next March will be of the highest quality, as always. I look forward to seeing many of you there and meanwhile wish you a very happy and healthy festive season.

Vanessa

US Law Update

James A. Thomas, Merck & Co., Inc., Whitehouse Station, USA

The US Trademark Trial and Appeal Board (TTAB) affirmed an Examiner's refusal to register VICORYX for pharmaceutical preparations for the treatment of cancer on the basis of VICEREX, which was registered for dietary supplements. In so ruling, the TTAB found the goods involved were related, noting the Examiner's evidence that dietary supplements were used in conjunction with cancer treatment, that both pharmaceutical preparations and dietary supplements were included together in numerous other registrations, and that cancer patients would be customers of both

goods. In re Oryx Verwaltungs GmbH, TTAB, Ser. No. 85823101, 9/2/2014 (non-precedential).

In a case of first impression, the TTAB recently ruled on the standard for determining abandonment for nonuse involving a Section 66(a) registration (under the Madrid Protocol). Under US trade mark law, non-use for three consecutive years constitutes prima facie evidence of abandonment. With respect to applications based on use or an intention to use, for which use is required prior to registration, this non-use period can be calculated at any time beginning with the applicant's

declaration of use, including non-use occurring prior to registration. In the case of a Section 66(a) registration, however, no use is required before registration. Therefore, the TTAB held that in a cancellation action based on non-use involving a Section 66(a) registration, the non-use period could not begin until at least the registration issues. Dragon Bleu (SARL) v VENM, LLC, TTAB, Opp. No. 91212231, 12/1/2014.

Words from the Chair



Once again, we are approaching the end of the year and our final issue of LL&P in 2014. In terms of PTMG Conferences, I think it is fair to say that 2014 has been a brilliant year!

To start with, we came back to London for the Spring Conference, after a (too) long absence from the British capital. This proved to be a great success and the quality of the presentations as well as the venue were commended. The level of service at the Savoy is definitely not a myth and it was a pleasure to be holding a Conference in such a magnificent hotel.

The continent on which the Autumn Conference would take place was the subject of many discussions within the PTMG Committee. Some of you might remember that the only time the PTMG organised a conference in the United States was in 2006, in Boston. Going back to the US for the second time was not an easy decision but the reality has proven that the Committee's decision was the right one. We had a remarkable Conference, and the feedback received was very positive:

“Magnificent Conference” –
“Congratulations on a fantastic meeting from beginning to end” –
“the presentations were outstanding” – “Sessions were very informative and interesting” –
“outstanding social events”.

One of our objectives was to gain a good attendance level from our US colleagues and it was so great to see many delegates from the States, including a significant number from the pharmaceutical industry. In particular, it was lovely to see some of our industry colleagues joining a PTMG Conference for the very first time and I hope it will only be the first of a very long series.

I wish all the PTMG community, your family and friends, a Merry Christmas and Happy New Year. I hope you will get a very well deserved end of year break.

Sophie Bodet

A Community trade mark law's perspective on suggestive signs

David E.F. Slopek, Hogan Lovells, Germany

Introduction

It is common practice to use trade marks for pharmaceuticals which are capable of providing prescribing doctors, pharmacists or other health professionals with certain information about the branded products. To give but two examples, Aspirin alludes to its active ingredients, i.e. A stands for acetyl and the syllable spir is derived from spireic acid. Likewise, Botox refers to its active ingredient botulinum toxin. Such signs are often referred to as so-called suggestive, evocative or allusive signs. In many cases they refer to the international nonproprietary name (INN) of the active ingredient. However, they can also refer to other characteristics of the drug, such as its indication, target group or means of administration. It is beyond question that health professionals are familiar with the existence of this naming practice in the pharmaceutical sector and that they can easily decipher the information conveyed in suggestive signs. However, it is often overlooked that when assessing the likelihood of confusion between two pharmaceutical trade marks, the consumer's understanding of such suggestive marks can tip the scales. This article explains why and how the consumer's view impacts on the legal assessment.

Why is the consumer's perception decisive?

Under Community trade mark law, it is crucial to assess the likelihood of confusion from the consumer's perspective. Initially, the General Court (GC) held that consumers may only be taken into account in the case of non-prescription drugs (GC, judgment of 13 February 2007 in Case T-256/04 [RESPICORT/RESPICUR], para. 45). Subsequently, the Court of Justice of the European Union (CJEU) held that even if the drugs are available in pharmacies only and despite the fact that the choice of those products is influenced or determined by intermediaries, the likelihood of confusion must also be assessed from the end consumer's perspective (Judgment of 26 April 2007 in Case C-412/05 P [TRIVASTAN/TRAVATAN], para. 58).

Meanwhile, it is well-established case-law that in the case of pharmaceutical trade marks, the relevant public comprises both end-consumers and health professionals even if the preparations require a doctor's prescription (GC, judgment of 9 February 2011 in Case T-222/09 [ALPHA D3/ALPHAREN], para. 43 et seq.).

For the assessment of the likelihood of confusion, the fact that the relevant public comprises both health professionals and end consumers cannot be overestimated. Whilst it is always easy to argue that the professional public is able to understand the precise meaning of conflicting signs and to grasp small differences which help differentiate between the conflicting signs, these arguments do not apply to end consumers. However, given that likelihood of confusion on the part of the public is sufficient, it is the end consumer's perception which is decisive for the assessment of the likelihood of confusion.

In particular, the argument that the mere coincidence in a descriptive or at least weak element does not suffice to cause a likelihood of confusion cannot be given any weight if one cannot establish that the relevant public understands the alleged descriptive meaning of an element. It is precisely for that reason that the GC recently annulled the Board of Appeal's decisions in the two parallel PENTASA/OCTASA cases, thereby highlighting that the Board failed to establish the descriptive character of the suffix -ASA from the perspective of the end consumers when carrying out the comparison of the conflicting signs.

Are consumers familiar with suggestive marks?

Having regard to the importance of the consumer's perception of suggestive signs, the question arises whether they are familiar with the common use of such marks in the pharmaceutical sector. If so, it is more likely that they will identify allusive elements when being confronted with the marks. Remarkably, in one judgment the General Court held that the applicant's submissions on the frequent use of allusive signs in the sector of therapeutic preparations cannot be

accepted", because, inter alia, they have not been developed (GC, judgment of 13 February 2007 in Case T-256/04 [RESPICORT/RESPICUR], para. 72). However, there are good reasons not to generalize this passage from a single judgment. In fact, OHIM's practice takes into account that allusive signs are very common in the pharmaceutical sector and, more importantly, that the consumer is used to this practice (see e.g. Board of Appeal, decision of 18 July 2013 in Case R 699/2012-1 [ANGIN-SAN/JUNIOR-ANGIN], para. 23).

What does the consumer understand?

In any case, the decisive question is not whether the consumer is generally aware of the widespread existence of allusive signs in the pharmaceutical sector, but rather if the consumer is able to understand the descriptive or allusive meaning of a specific sign. The answer to this question depends on the circumstances of the specific case. Consequently, it does not come as a surprise that the relevant case-law does not rely on general guidelines, but appears rather casuistic. With that being said, the following decisions are supposed to give some hints as to the GC's approach to assess the end consumer's understanding of suggestive signs.

The GC has taken the view that the end consumer is capable of understanding RESPI as a reference to respiratory (GC, judgment of 13 February 2007 in Case T-256/04 [RESPIRORT/RESPICUR], para. 71 et seq.); VISC as a reference to viscosity (GC, judgment of 10 September 2008 in Case T-106/07 [PROVISC, DUOVISC/BIOVISC], para. 40); NICO as a reference to nicotine (GC, judgment of 6 June 2013 in Case T580/11 [NICORETTE/NICORONO], para. 30); CHOL as a reference to cholesterol (GC, judgment of 12 July 2012 in Case T-517/10 [HITRECHOL/HYPOCHOL], para. 27) and ECHIN(A) as a reference to the Latin name of the plant Echinacea (Court of First Instance, judgment of 5 April 2006 in Case T-202/04 [ECHINACIN/ECHINAID], para. 44).

Whilst the above-mentioned examples could indicate that the consumer has a (partly surprisingly) good understanding of suggestive terms, there is also case-law pointing in the opposite

direction. By way of example, the GC held that the consumer will not understand CORT as a reference to corticoids (GC, judgment of 13 February 2007 in Case T-256/04 [RESPIRORT/RESPICUR], para. 71); VIR as a reference to antiviral (GC, judgment of 13 September 2010 in Case T-149/08 [NORVIR/SORVIR], para. 39) or Latin or Greek terms such as MENO or CHRON (GC, judgment of 28 April 2014 in Case T-473/11 [MENODORON/MENOCHRON], para. 39).

In some cases, the GC also put emphasis on the rule that the consumer generally perceives the mark as a whole, so that it is harder for the end-user to grasp any descriptive meaning of an element, if it is part of a single word (see to this effect GC, judgment of 9 April 2014 in Case T-501/12 [PENTASA/OCTASA], para. 50; the GC adopted a similar reasoning in its judgment of 13 September 2010 in Case T-149/08 [NORVIR/SORVIR], para. 39).

Summary

Case-law establishes that the likelihood of confusion between two conflicting trade marks has to be assessed from the perspective of the relevant public. In the case of pharmaceutical trade marks, the relevant public comprises both health professionals and end consumers. With respect to end consumers, the decisive question is if they understand the descriptive meaning of certain elements within suggestive marks. If so, there is room to argue that the element is weak and that the mere coincidence in such elements is not sufficient to cause a likelihood of confusion. There is extensive case-law on the whether and, as the case may be, to what extent consumers understand the descriptive or allusive meaning of suggestive marks.

Whilst it can be difficult to predict whether the GC will regard an element as descriptive or not, precise knowledge of the relevant case-law and OHIM's practice is not only very helpful, but can actually make the difference between winning or losing a case.

International Update

Hungary

PETOSEVIC

The Budapest police authorities have recently discovered and seized almost 170,000 pieces of counterfeit medicines in the basement of a building in Budapest. The police arrested a 45-year-old man on suspicion of counterfeiting pharmaceutical products.

On 21 October, 2014, the Budapest police received a tip that a man will probably buy narcotics at a certain address in the 3rd district of Budapest. The police went to the site where they checked the identity of two men found standing next to a car. The owner of the car was the 45-year-old man. The police searched the car and discovered several hundred bottles labelled Rivotril, filled with counterfeit pills, as well as pills in unmarked bags, several hundred unmarked bottles, and a bag with white powder of unknown composition.

The police discovered that the suspect owns keys to certain premises in the 22nd district of Budapest. After searching the premises, the police discovered large quantities of Rivotril 2mg labels, empty bottles, bottle caps, cotton balls, digital scales, label applicators and other equipment used for making counterfeit drugs.

The criminal procedure is underway.

Hungary

PETOSEVIC

The Hungarian National Board Against Counterfeiting announced on its website that in the next few years, European Union member states are expected to implement a stricter prescription drug monitoring system, aimed at preventing counterfeit medicines from entering the supply chain, based on the Falsified Medicines Directive, which will enter into force in 2018 in the EU.

According to the Directive, each drug package will need to be tamper-resistant and coated with a unique two-dimensional barcode, containing manufacturer's code, serial number, national healthcare reimbursement number, batch number and expiration date. These measures will make

unauthorized access to the protected package easily detected and allow genuine packs of drugs to be traced back to manufacturers and distributors.

Every prescription drug package will have to be registered in the common EU database from which it can only be removed if purchased by pharmacies or used in hospitals. To comply with the new system, the EU member states will need to introduce major IT-related changes, some of which may be complicated or time-consuming to implement. Some estimates say that this will affect 17 billion boxes of prescribed medicines per year, which come from 4,600 manufacturers and reach 177,000 distribution places.

Hungarian experts are somewhat concerned about these big changes, especially since in Hungary counterfeit pills have never got into the legal medicine chain, i.e. manufacturer – retailer – pharmacy/hospital/doctor.

“The best practice would be to gradually develop the IT system, starting with the most narrow medicine circle first, which means fewer packages with safety features and more drugs on the exception list”, stated Dr. Livia Ilku, head of the Hungarian Pharmaceutical Manufacturers Association.

India

Sharabh Shrivastava, CHADHA & CHADHA

In a recent decision dated 12 September, 2014 involving pharmaceutical products in the matter of Sun Pharmaceutical Industries Limited v Anglo French Drugs and Industries Limited, the Division Bench of the Delhi High Court while holding OXETOL to be dissimilar to EXITOL opined that slight semblance of phonetic similarity between two marks would not automatically satisfy the test of confusion to a man of average intelligence having imperfect recollection and it is necessary that the marks are compared as a whole.

The quintessence of the decision of the Appellate Court lies in the fact that the court, while determining the question of similarity between two marks, relied more on the entire visual representation of the two pharmaceutical products rather than considering the marks to be words per se. Further, what seems to have guided the court to hold OXETOL to be dissimilar to EXITOL is that EXITOL was sold in syrup and granule form whereas OXETOL was sold in the form of tablets or capsules.

Moreover, OXETOL was being sold in blister packs whereas EXITOL was being sold in bottles or sachets. The graphics on the OXETOL pack displayed a man and his brain, clearly representing that this was a drug for treating a brain disorder whereas on the EXITOL pack, the graphics showed an intestine, which again showed that the drug was directed to treat an intestinal disorder (constipation). Further, the graphics on the OXETOL product was in orange script on a white background and the use of the color brown whereas on the EXITOL pack there was a yellow and white color scheme and EXITOL was written in a distinctive blue script. Both drugs were available on prescription basis only. In the case of OXETOL, the prescribing doctor would be a neurologist, whereas in the case of EXITOL it would be a physician at a hospital, EXITOL being a hospital administered laxative.

The Court further observed that the consuming patients would also be different, neuro patients in one case and in the other case patients suffering from intestinal disorders who were admitted to a hospital.

The decision interestingly lays emphasis on an important factor of visual representation while determining the question of deceptive similarity in the The decision interestingly lays emphasis on an important factor of visual representation while determining the question of deceptive similarity in the context of pharmaceutical products as patients in India may differentiate between the products based on the visual representation of packaging or colour scheme of the drug rather than discerning or comprehending the word element mentioned on the packaging.

In view of the varying infrastructure for supervision of physicians and pharmacists of the medical profession in our country due to linguistic, urban, semi-urban and rural divide across the country and with a high degree of possibility of even accidental negligence, this decision certainly comes at an opportune time. It directs to take into account significant consequential factors namely active ingredient, product form, packaging, artwork/ graphics, visual impression, disease condition, prescribing doctor, purchasing public, consuming public and price in addition to merely comparing the word element while determining the question of deceptive similarity of marks in the context of pharmaceutical products in India.

Members News

New Members

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

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Moves and Mergers

Isabelle Dini has left Norgine to join L'Oreal in London, UK. Isabelle can now be contacted at Isabelle.DINI@loreal.com

Erratum

Patrick Van de Vorst is now with Corsearch who are based in Mechelen, Belgium, not Edegem as reported in the previous edition of LL&P.

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

Faster, safer and more attractive? OHIM introduces “Fast Track” Application System

Dr Birgit Clark, Trade Mark Attorney, London

On 24 November 2014, the Office for Harmonisation in the Internal Market, the European Union’s trade mark office, (OHIM) introduced a new fast track trade mark application procedure for Community Trade Marks (CTMs). This optional new route is generally expected to considerably shorten the time from filing to registration and thereby increase the attractiveness of the CTM route. So how does it work, what conditions will have to be met to qualify for the fast track and what are the expected practical consequences?

The Community trade mark system: a brief overview

By way of reminder and background, a quick overview of the CTM system. In a nutshell, a CTM offers its owner trade mark protection throughout the whole of the European Union. CTMs are registered at OHIM and give their owners protection in all 28 EU member states in one single trade mark and thus a single, unitary registration, enforceable throughout the EU. As OHIM states on its website, a CTM is an “all or nothing deal”: either you get it for all member states or you do not get a CTM at all. CTMs are usually considered a very cost effective route for applicants that seek pan-European trade mark protection but may not always be the right choice for an applicant. National trade mark systems in the EU member states operate alongside the CTM system and OHIM joined the Madrid Protocol on 1 October 2004, meaning that a CTM can also be designated in an International Registration. The registration process at OHIM has traditionally been rather fast with OHIM most notably not citing earlier marks as obstacles to registration: on average the examination period for a CTM is about 8-11 weeks. Once the examination procedure has been successfully concluded, the mark moves forward to publication giving third parties an opportunity to oppose registration within three months from the date of publication.

OHIM’s new Fast Track System

As of 24 November 2014 OHIM has now introduced an optional fast track application procedure, which is intended

to further accelerate its already quite speedy examination process. While the new fast track procedure will not shorten the three months opposition period for CTM applications, the new procedure is meant to be “faster” as well as “safer”: faster since only applications that comply with certain conditions are eligible for the fast track (more on this below). If they do comply, applications can be published in half of the time or less compared with regular applications. Safer, since applicants may only select pre-translated and pre-validated terms of goods and services from OHIM’s harmonised database. The terms in this database have been approved by OHIM as well as virtually all the international property offices in the EU. Using terms from this database, - even outside the fast track system - therefore reduces the likelihood of deficiencies and allows a smooth processing of the application. OHIM has also developed a dedicated 5-step online application form, which includes mandatory options that are meant to ensure that the application is processed on the fast track. Helpfully, the application form flags whether or not an application complies with the fast track conditions and also proposes corrections which render an application suitable for the fast track. It should be noted however that CTM applications may fall outside the fast track system after filing, e.g. if the mark falls foul of any of the absolute grounds of refusal, such as lacking inherent distinctiveness.

How to qualify for the fast track?

To qualify for the fast track, a CTM has to, inter alia, meet the following (additional) cumulative conditions. Notably, the filing fees will not increase for a fast track application.

- The applicant has to be domiciled in the EU or appoint an EU representative;
- The application has to be for a word, figurative 3D or sound trade mark (i.e. not a collective mark);
- Goods/services have to be selected from OHIM’s harmonised database of pre-validated and pre-translated terms;

- No request for national searches can be included;
- If priority is claimed, the priority certificate(s) must be included upon filing;
- Filing fees have to be paid upon filing the application.

Concurrently with the introduction of the fast track system, OHIM has also announced that CTM applications will now only enter the examination process once the official filing fee has been received at the Office. Whilst it is still possible to delay payment for one month following filing, OHIM decided to introduce this change to prevent speculative applications for borderline non-distinctive/descriptive signs, which in the past may have been examined and potentially refused before the official filing fee had been paid. According to OHIM, in 4% of all cases, applicants had used this convenient option and received an examination report without having paid the official fees. For fast track applications, users therefore have to select the “debit now” button on OHIM’s 5 step application form.

Practical significance

OHIM’s new fast track process is designed to make the CTM route even more attractive, especially for those applicants that are happy to draft their specification so that it only includes the pre-approved terms from OHIM’s database. For some applicants this may lead to the drafting of standard specifications consisting entirely of pre-approved terms. However, this may not always be suitable, especially in the pharmaceutical industry, where specifications often are “bespoke” and/or claim priority from other jurisdictions, where the priority mark may not include pre-approved terms under OHIM’s practice. OHIM’s fast track system should, nonetheless, allow for an increased number of CTMs achieving registration within the six months priority period under the Paris Convention, which could in turn make CTMs more attractive as a basis for International trade marks.

PTMG 89th Conference, Chicago October 8th - 11th

The Multi-Faceted Personality of a Pharmaceutical Trade Mark

Rigel Moss McGrath, W.P.Thompson & Co.

Chicago has been described as "perhaps the most typically American place in America" and so what an inspired choice by the PTMG Committee to host the 89th PTMG conference, visiting the USA for only the second time in its history. If any of the attendees were feeling the effects of a longer journey than usual, there were no signs of it as we gathered in the ballroom of The Drake Hotel to greet old friends and make new ones at the Welcome Reception on Wednesday evening.



Sophie Bodet

On Thursday morning our Chairman Sophie Bodet introduced and thanked the Committee members and welcomed the attendees, including more than 100 'first timers', many from the pharma industry. The conference had been fully booked at an early stage but Sophie assuaged any concerns that the Committee had plans to make the conferences 'bigger'. So many members appreciate the very 'manageable' size of the event and this reassurance was welcomed.

PTMG conference presentations are renowned for their quality and relevance and this year did not disappoint at all, beginning with the Founder's Lecture. Created to honour and celebrate the founding of the organisation by Derek Rossitter, who unfortunately was unable to attend this conference, each year a young and rising lawyer is selected to present the Founder's Lecture. This year that honour fell to Christopher Hanes, Senior Counsel for GSK, who provided a comprehensive overview of the historical and current challenges specific to the requirement for 'use' of pharmaceutical trade marks in the USA. The registration of these marks can be difficult in any territory (with very lengthy lead times and

the need to balance the requirements of trade mark applications and regulatory approval) but where registration is treated simply as the recognition of rights acquired by common law, as in the USA, obtaining registration becomes more challenging. There is a clear advantage to be exploited by the brand owner that can base their application on an earlier regis-



Christopher Hanes

tration elsewhere, rather than use in the USA; but of course under US law the requirement for 'use' affects all stages of the life cycle of a trade mark registration - at some point the owner will have to provide specimens of use and Christopher provided helpful examples of what is likely to satisfy. Finally Christopher introduced a theme that was picked up throughout the conference, namely the conflict between national trade mark offices and regulatory bodies, which apply different tests to assess the availability and approval of trade marks. A clear (and robust) strategy is required to navigate corresponding applications to a successful outcome for the client.

Kellie Taylor's review of recent developments in the Food and Drug Authority (FDA) approval of proprietary names provided an excellent insight into a system that was surely unfamiliar to many in the audience - and yet it became quite clear that it is important for attorneys to understand its workings if we are to provide truly comprehensive advice on the registrability of pharma trade marks. One would expect the examination process to be stringent, but it was still fascinating to be led through the complex layers of analysis applied to each proposed name, including of course searches of drug names used outside the US. Whilst there is some international cooperation



Kellie Taylor

between regulatory authorities, each has its own considerations. Interesting too was the contrast between the trade mark application and FDA name approval systems, the first being a 'first to use' whilst the second is a first to register system.



Gail Karet

Gail Karet, Rafaella Balocco Matavelli and Antoinette Lachat made up the panel of experts that provided a set of lively, informative and entertaining presentations and discussions. Rafaella really brought the subject of non-proprietary names to life in her presentation on the WHO INN Programme. We were an unusual audience to consider the selection process for non-proprietary names - names that belong to everyone and through which they cannot make money! However the INN programme does not work within a vacuum and pharma companies necessarily need to work with it from a marketing perspective in respect of which there appears to be a settled approach of "they do their business and we do ours." Gail provided a very practical overview of the



Raffaella Balocco Matavelli

activities of the USAN program, with which relatively few in the audience will have had direct engagement and yet the considerations are very familiar; from a marketing perspective each pharma company wants to establish a new non-proprietary name to indicate a new and



Antoinette Lachat

revolutionary drug, but of course these are more meaningful if there are fewer of them.

The panellists acknowledged that there are serious limitations to the effectiveness of the programs that had been discussed and it was hard not to be struck that this seemed at such odds to the importance of the work they were doing. There seems to be a dangerous lack of cooperation between trade mark offices and regulatory bodies and yet, for example, INN is dependent upon national authorities implementing what are in effect only recommendations. India was cited as a country that posed particular problems as it appears to be reluctant to understand the INN programme and what it seeks to achieve and yet this is such a crucial territory to the pharmaceutical industry as a whole. The risks were clearly highlighted by some truly frightening examples of trade marks so similar to non-proprietary names as to create a genuine risk of confusion,

provided during Antoinette's presentation on the importance of non-proprietary names to industry. Antoinette also outlined future challenges from the industry perspective and one could but agree that the world is going to become increasingly complicated for those that want to bring their drugs to the market.



Carmen Catizone

The focus shifted slightly as Carmen Catizone presented details of the background and purpose of the .pharmacy gTLD. A frightening proportion of pharmaceuticals are sold direct to the consumer via the internet, creating complex problems for the regulatory authorities. Despite clear and serious risks, increasing numbers of consumers place both their health and financial information on the internet, but it seems that the .pharmacy gTLD has the potential to provide some genuine protection by creating a safe and legitimate marketplace. There is global support for .pharmacy, but it will only succeed if the authorities can maintain continuous compliance monitoring, pharma companies invest in the domain and, crucially, there is significant joint investment in consumer education.



Jonathan Jennings

Jonathan Jennings' presentation comprehensively covered the interplay

between trade marks and identity rights in the USA, where identity rights are granted strong protection under statutory provisions. By way of contrast the UK is still fumbling with the protection of identity rights by way of 'false endorsement', a form of 'passing off'. In a world that seems to be increasingly subject to the power of social media, which acknowledges few if any borders, the conflict between legal systems is a source of increasing concern.

To a visitor from Europe (or as I was to learn from anywhere other than New Zealand) the prevalence of direct to consumer advertising of pharmaceutical



Anthony Genovese

products in the USA is astonishing and Thursday's final presentation, made by Anthony Genovese, provided an entertaining and informative overview of the subject. There appears to be a reassuring system of validating claims within adverts and there is no doubt that the pros and cons of DTC advertising are well balanced. Whilst I remain bewildered by the idea that a lack of 'eyelash fullness' could be considered a 'medical' condition, by the end of Anthony's presentation my understanding and indeed appreciation of DTC had increased considerably.

On Thursday evening delegates headed to Lake Michigan for an evening cruise. It was a wonderfully relaxed environment and we were accompanied by an excellent Chicago blues band as we travelled along the shoreline. It is a universal fact that no matter how old one gets, fireworks still have an almost magical effect and although the air was crisp most delegates enjoyed a glorious display from the deck.



Jacques Labrunie

On Friday morning Jacques Labrunie drew our attention away from the USA temporarily, to Brazil, the focus of considerable international attention with the world cup a recent memory, a forthcoming general election and the build up to the Olympics, in less than 2 years, underway. The supply of pharmaceutical products in Brazil is an important issue; it is a large and growing market with over half of the population regularly taking medications, which are expensive to the extent that price is inhibiting use. In common with the USA (and many other territories) there is conflict between the trade mark and regulatory authorities. Trade mark registration is only the first step in the regulatory process, taking 2-3 years before the trade mark is placed before the regulatory authority, ANVISA, where the proposed mark is examined on different grounds. A lack of harmonisation between the systems is so extreme that, for example, the cancellation of a trade mark registration may not be recognised by ANVISA. Again, it is difficult to make sense of such conflict in these circumstances.

Negotiations are underway to change the regulatory landscape in Brazil, but there is perceptible frustration caused by the slow pace of change and genuine concerns that ANVISA has stepped back from a protection role, leaving the BPO to fill the void in protection, which is contrary to the position in almost all other territories. (see article on page 11).

Steven Garland brought us back to North America, with another highly topical matter, the long awaited changes to Canadian trade mark law, which should come into force at the end of 2015/2016. The proposed changes are intended to make it easier, faster and cheaper to obtain trade mark registration and to make the system more similar to

that of other territories. The proposed changes are fundamental in nature; the very definition of a trademark is to be amended to incorporate a broad range of non-traditional marks, the requirement for use before registration is granted is to be removed and a classification system



Steven Garland

will be introduced, which will also enable participation in the WIPO system. Whilst this is all positive the removal of the use requirements will create an environment welcoming to trade mark squatters and those trade mark owners who have relied upon unregistered rights are urged to formalise those rights before the introduction of the new provisions. Steven provided some practical guidance as to the kind of cases that may be more effectively prosecuted before the new laws are enacted, such as the formal protection of unregistered rights and applications claiming multiple class specifications. I am sure that many of us will look forward to updates at future PTMG meetings.



James Thomas

We moved very firmly back to the USA for the next presentation, an examination of US trade mark law and the First Amendment, focusing upon the right to

use trade marks as a form of free speech. It often feels as if the USA is in almost constant state of pre-election fever, and I became familiar with a number of campaign adverts during the conference which provided a very relevant backdrop to James Thomas' presentation, which began with an examination of political speech and artistic expression protected by the First Amendment. James then turned to the use of pharmaceutical trade marks as a form of 'commercial speech'. Currently trade mark applications are not subject to First Amendment analysis, primarily because the application process does not concern use of the mark. However the same cannot be said for cancellation cases which can raise constitutional issues. It



Tom Farrand

was a fascinating insight into considerations of which I had not previously been aware.

In contrast Tom Farrand's presentation on brand valuation concerns a matter at the very core of our profession throughout the world. Whilst formal brand valuation is undertaken by accountants and analysts wielding complicated formulas, the notion of a brand as a 'valuable' asset is one that we work hard every day to reinforce - "What gets measured gets managed" indeed! Tom's comparison of intangible/tangible assets of pharma companies was striking, but perhaps more so was the comparison of the value of pharma brands to technology brands. Could there be any better cue to set out very practical advice concerning portfolio management and its direct impact upon brand value?



Rob Litowitz

I must confess that prior to Rob Litowitz's highly engaging presentation I had given (at best) limited consideration to the concept of 'floating brands', but I have now been duly educated and I find myself far more sensitive to their use by innovative brand owners! A 'fluid brand' goes beyond the normal evolution of a brand and is best exemplified by the 'Google Doodles'. Fluid brands are used to good effect in vastly different areas of commerce including technology, drinks manufacturers and retailers. Clearly brand owners must be mindful to avoid abandonment, but the examples provided demonstrated how effective use of fluid brands can be. Their popularity with brand managers is unlikely to wane and this is an area of brand protection that we as attorneys need to embrace.



Toe Su Aung

At the beginning of her presentation, having polled the delegates, Toe Su Aung expressed surprise at our lack of awareness of The Medicrime Convention and proceeded, very successfully, to rectify the situation. The Convention seeks to provide a legal framework to make the counterfeiting of medicines (whether protected by IPRs or not) a

criminal offence in as many countries as possible. Perhaps our lack of awareness stems from the fact that the convention is not based upon existing IP laws (to the extent that the definition of 'counterfeit' is subtly different) and shifts the basis for action away from IPRs to product safety. It is not yet in force and there seems a frustratingly long way to go before all 28 Member States of the EU ratify the Convention; but we were urged to encourage our Governments to make progress and in this respect the Pharma industry will play a key role! The presentation created considerable discussion, particularly by way of comparison with and the lessons to be learned from ACTA.



Bruce Longbottom

Fittingly the final presentation of the conference focused on the USA and the continuing fight against counterfeits. During his presentation Bruce Longbottom introduced the DQSA, ASOP and CSIP to the audience, in the process neatly echoing some of the issues that had been identified in earlier presentations. Statistics concerning the online market for counterfeit goods continue to stagger me, as do the examples of sophisticated online marketing of counterfeit products, which demonstrate how easy it must be for the consumer to feel confident that they are purchasing goods from a reputable regulated vendor. Whilst Government enforcement agencies have imposed huge fines upon third parties such as Google and UPS, given the value of the business generated by illicit online pharmacies, it is clear that those fines will need to be even greater in size if they are to have a meaningful effect on the counterfeit drugs market. This is another topic on which I look forward to receiving updates at future conferences.

To conclude, the presentations were excellent, without exception, tackling varied and often complex subject matters and making them understandable and relevant. I recommend accessing the presentation slides whilst they remain available and, as always, look forward to the next conference to be held in Venice in March 2015.

The Gala dinner, held at the Museum of Science and Industry, was a great venue to end the conference in style. Many delegates took the opportunity to visit the exhibitions which were open for our visit, the most spectacular of which was a U-505 submarine.



Sophie Bodet presents The Founder's Lecture Award to Christopher Hanes on the morning of Day 1

PTMG 90th Conference

Venice

23rd-24th March 2015

Registration will open on PTMG website in mid January 2015

New rules about names of pharmaceutical products enacted in Brazil

Gustavo Piva de Andrade, Dannemann Siemsen

In October 2014, the Brazilian Health Surveillance Agency (ANVISA) enacted Resolution RDC n° 59/2014 setting several criteria for the formation of names for pharmaceutical products.

The new rules are likely to cause a significant impact to the practice of the pharmaceutical industry. As a result, it is imperative that regulatory and IP professionals are aware of the new regulations enacted by the Brazilian health surveillance authorities.

The purpose of this article is to provide an overview about Resolution RDC n° 59/2014 and comment about the aspects which should be considered in the selection and adoption of drug names by a pharmaceutical company.

It also examines the Resolution from a practical perspective, shedding light on the interface between the new rules and some fundamental tenets of trade mark law.

Reach of the new Resolution

Firstly, an important disclaimer: Resolution RDC n° 59/2014 makes clear, in its article 20, that product registrations granted under the prior rules will not be reviewed by ANVISA.

This means that the new regulation does not affect already granted registrations and will be limited to future registrations or to product applications that have not yet been approved by the agency.

Pharmaceutical companies therefore do not need to bring into line existing product registrations to the new rules, which denotes ANVISA's praiseworthy concern to protect vested rights.

Criteria for names of pharmaceutical products

Resolution RDC n° 59/2014 brings forth two positive aspects in respect of the names of pharmaceutical products.

The first refers to terminology. ANVISA has finally abandoned the term "trade name" to refer to the trade mark of a pharmaceutical product. From now on, ANVISA will use the term "drug name", which is more appropriate than its predecessor, since the term "trade name" is commonly used as a synonym of "corporate name" in Brazil.

The second good news is even more important: the new Resolution revokes the "3-letter rule", according to which "the name of a medication could be similar to an already registered name as long as they differ in at least 3 different letters".

That rule was in blatant disagreement with traditional principles of trade mark law. After all, there might exist confusingly similar trade marks that differ in three or more letters and sufficiently distinct marks that differ in just two.

Thus, ANVISA acted correctly in revoking the 3-letters rule and replacing it by section 7, sole paragraph, of the current Resolution. This section provides that "the intended drug name must have sufficient graphic and phonetic distinction in relation to the names of other registered drug products".

As seen above, the current rule mandates that the name to be registered before the agency must be graphically and phonetically different as opposed to prior registered names.

Although other criteria could have been added, this is unquestionably an improvement in respect of the prior rule, since the conflict assessment between two names should be done on a case-by-case basis and should not be governed by mathematical standards.

The new Resolution also provides that the trade mark of a pharmaceutical product should preferably comprise only one word and its intended pronunciation in Portuguese must have direct relation to its spelling.

The existence of the term "preferably" indicates that the one-word structure is not mandatory.

The spelling rule, in its turn, indicates that ANVISA can reject names that can cause certain inconsistencies as to the way they are spoken or written.

For example, when seeing the mark THERAHAIR identifying a medication used to stimulate hair growth, a Brazilian consumer familiarized with the English language would probably face no difficulty in pronouncing the term correctly.

The same, however, would probably not occur with a consumer who is not acquainted with the English language, since when positioned in the middle of the word, letter h produces no sound in Portuguese.

It is precisely this kind of inconsistency that ANVISA seeks to avoid. As a result, it is imperative that pharmaceutical companies take this rule into consideration while selecting a new mark to be used in the Brazilian market.

Prohibitions set forth by the new Resolution

Resolution RDC n° 59/2014 provides, in its article 15, that trade marks of drug products and their complements cannot use:

- The suffixes of nonproprietary names recommended for each therapeutic class of pharmaceutical substances, even if in a position different to that usually recommended – this rule prohibits the use of suffixes recommended for each therapeutic class of the pharmacology, such as -ADOL for analgesics and CICLOVIR for antiviral compounds (according to the Manual of the Brazilian Nonproprietary Names);
- The parcel of the nonproprietary name of the drug substance, usually associated with a particular active

ingredient, when it is not part of the drug product composition – the aim of this rule is to guarantee that the parcel of the non-proprietary name associated with a particular active ingredient is only used when the active ingredient is present in the medication. The term TAMOL therefore, can only be used in connection with medications which have paracetamol as an active ingredient;

- Abbreviations, isolated letters, random sequence of letters, Arabic or Roman numbers, without clear meaning to the consumer or that do not have any relation to the features of the product – this rule is self-explanatory and can be used to prevent the use of terms and abbreviations that do not have a clear meaning to the Brazilian consumer; and can be used to prevent the use of terms and abbreviations that do not have a clear meaning to the Brazilian consumer;
- Names that do not correspond to the way the drug product is given – the goal of this rule is to prevent confusion as to the pharmaceutical form of the drug or as to how the medication is administered. Thus, for instance, the terms spray or lotion cannot be used in connection with a liquid preparation administered orally;
- Words or expressions that may lead to the understanding that the drug product is innocuous, natural, exempt from or with reduced side effects, or that the drug product has superior potency and quality or unproven special properties – this rule prohibits the use of expressions such as NATURAL, SOFT and LIGHT or any other term that may lead the consumer into doubt or error as to the features of the medication;
- Words or expressions that emphasize a therapeutic action, without evidence from clinical studies, and that may lead the consumer to believe that such drug product has superior therapeutic effect as opposed to another drug product of equal composition – this rule forbids the use of terms such as MAX, PLUS, SUPER in

connection to variations of an existing medication, unless the manufacturer is able to prove that the variation is indeed superior to the prior one;

- Name of drug product that has been rejected due to efficacy or safety reasons.

Finally, the Resolution provides that, when evaluating other cases not included in the prohibitions, ANVISA may still reject the proposed name when it detects any sanitary risk to the consumer.

Families of drug products

Resolution RDC n° 59/2014 fortunately embraces the concept of families of drug products. It provides that drug products of the same company, whose formulation contains the same active ingredient, may be grouped in families sharing the same mark and adopting complements that distinguish the drug products.

The Resolution also mandates that the exclusion or replacement of the active ingredient demands the adoption of another mark for the medication. Thus, consider a family of analgesics whose active ingredient is ibuprofen. If the manufacturer replaces the ibuprofen by dipyron in one of the products, the mark of that product would have to be changed, in a manner to adopt a different mark as opposed to the family.

The exceptions are the multivitamin, multimineral and multi amino acid products. In these cases, the mark of the family can be maintained, but the manufacturer should use complements indicating the target public of the product.

Criteria for complements of names of drug products

Finally, Resolution RDC n° 59/2014 regulates the use of complements in pharmaceutical trade marks, pointing out that the complements must be used to distinguish certain medication from other medication registered by the same company, within the same family of products.

In respect to these complements, the Resolution provides that:

- ANVISA will not consider, for purposes of registration, the existence of exclusive rights over the name complement – this means that, in principle, the agency will presume that the name complement cannot be appropriated. Thus, if the company believes that the complement is distinctive and able to function as a mark, it should take judicial measures to avoid the inclusion of the complement in subsequent third party registrations;
- Using the same name complement with different meanings is prohibited;
- Pharmaceutical companies can, upon substantiated justification, use name complements to distinguish routes of administration, pharmaceutical forms, target groups and absorption details of the drug products;
- Drug products presenting kinetics of different release, different pharmaceutical forms or different routes of administration within the same family must adopt name complements.

Conclusion

ANVISA's new Resolution regulates several aspects relating to the names of pharmaceutical products. Some changes are quite positive, such as the abolition of the 3-letters rule, a test which was severely criticized by the pharmaceutical industry and the entire trade mark community.

On the other hand, the Resolution brings some specific provisions to the current regulatory scenario. This is extremely relevant because the rejection of the application can obstruct the launching and sale of the drug product in the market.

Pharmaceutical companies operating in Brazil therefore, should be attentive to these rules and create an efficient interaction between their regulatory and intellectual property departments.

Approval of proposed invented names for medicinal products in Slovenia

Ms. Tatjana Simovic, PETOSEVIC

The regulatory framework in Slovenia allows prescribing of medicines by their international non-proprietary name (INN). However, as INN prescribing is not compulsory, physicians mostly prescribe medicines by their invented names. Pharmaceutical branding thus plays an important role in marketing of pharmaceuticals in Slovenia.

The competent authority in Slovenia responsible for granting marketing authorisations through the national, decentralised or mutual recognition procedure is the Agency for Medicinal Products and Medical Devices of the Republic of Slovenia (hereafter referred to as the JAZMP). Part of its role in evaluating the safety of medicinal products is to approve their proposed (invented) names. In that regard the JAZMP issued the Guideline governing the acceptability of names for human medicinal products (hereafter referred to as the JAZMP Guideline).

The JAZMP Guideline mostly follows the requirements for approval of proposed (invented) names in the process of granting Community marketing authorisation for human medicinal product through the centralised procedure that is in the competence of the European Medicines Agency (hereafter referred to as the EMA). A Community marketing authorisation for human medicinal product is valid throughout the European Union and the invented name of the medicinal product is an integral part of the authorisation. According to Article 1(20) of Directive 2001/83/EC, as amended, the name of the medicinal product “may be either an invented name not liable to confusion with the common name, or a common name or scientific name accompanied by a trade mark or the name of the marketing authorisation holder”. Article 6(1) of Regulation (EC) No 726/2004 stipulates that a single name is used to identify a medicinal product authorised under the centralised procedure.

For the purpose of reviewing proposed (invented) names of medicinal products,

the EMA established the (Invented) Name Review Group (NRG) composed of representatives from the EU Member States. The group's main role is to consider whether the invented name proposed by the applicant(s) or marketing authorisation holder(s) could create a public-health concern or potential safety risk. When assessing the acceptability of the proposed (invented) names, the NRG applies criteria based on public health concerns and, in particular, safety. Specifically, the invented name should not:

- convey misleading therapeutic or pharmaceutical connotations;
- be misleading with respect to the composition of the product;
- be liable to cause confusion with the invented name of an existing medicinal product in print, handwriting or speech.

The criteria applied by the NRG when reviewing the acceptability of proposed (invented) names are detailed in the Guideline on the acceptability of names for human medicinal products processed through the centralised procedure (EMA/CHMP/287710/2014 – Rev. 6), hereafter referred to as the EMA Guideline.

In reviewing the proposed (invented) names of medicinal products authorised through the national, decentralised or mutual recognition procedure, the JAZMP takes into consideration safety issues and possible confusion with existing medicinal product names or names pending approval. As of late 2011 an increase in the rejection rate with respect to the names proposed to the JAZMP is noticeable. The JAZMP decisions on the proposed (invented) names often seem arbitrary, which is evident from the situation on the market.

The JAZMP Guideline introduced a requirement not comprised in the EMA Guideline prescribing that the names of medicinal products should differ in at least three characters. This criterion is vague

and may be interpreted in different ways. According to one possible interpretation, the names of two medicinal products must differ in more than three letters, whereas the letters are compared in the sequence as they appear. The same requirement may also be interpreted in a way that the names of two medicinal products must differ in three or more letters, whereas the positioning of the individual letters is not taken into account. The JAZMP has not made publicly available its official standpoint on this issue. There are examples of name pairs that have been approved by the JAZMP that do not fulfil the aforesaid requirement, regardless of the interpretation applied, e.g. TOBEX and TOBRADEX, ZALDIAR and SELDIAR. The applicants for marketing authorisations often face rejections of the proposed invented names of medicinal products due to the alleged similarity to the applied/registered invented name, even though the conflicting names are more distant visually and phonetically than the aforesaid name pairs.

Furthermore, trade mark registration priority is not a determining factor in the JAZMP assessment of the acceptability of the proposed name for a human medicinal product. Since the first-come, first-served rule is applied, the proposed name enjoining the trade mark registration priority can be rejected during the marketing authorisation granting procedure on the basis of a name that obtained trade mark protection later, but for which marketing authorisation was requested earlier.

The applicants have the possibility to consult with the JAZMP as regards the acceptability of the proposed (invented) name prior to filing an application for marketing authorisation. However, the opinion given beforehand is not binding in the granting of marketing authorisation, and it neither helps in anticipating the outcome of the assessment of each proposed name nor does it remedy the JAZMP's strict and inconsistent practice.

PROFILE: Joëlle Sanit-Hugot

Joëlle Sanit-Hugot has been working in the pharmaceutical sector for more than 25 years and exclusively in the area of Intellectual Property law for over 20 years.

From the start of her career, she has worked continuously in various predecessor companies to SANOFI, and spent two years as the Head of the Company's Trade Mark Department in Germany. She now holds the position of Deputy Director of the Trade Mark Legal Department, based in France,

Joëlle is on the PTMG's Management Committee. She is also a member of APRAM (Association des Praticiens du Droit des Marques et des Modèles), and of several pharmaceutical related associations, such as EFPIA (European Federation of Pharmaceutical Industries and Associations), and Leem (Les Entreprises du Médicament) – for which she is the Chair of the Trademark Ad Hoc Group.

She has spoken at national and international conferences such as APRAM, PTMG, INTA, ASIPI.



Where were you brought up and educated ?

In Paris - France.

How did you become involved in trade marks ?

While studying law at University I attended an IP Class. I was particularly interested in trade marks and decided to select IP as my specialization for my Law Degree.

I was already working at Roussel Uclaf during this time and, when a position for a trade mark lawyer became vacant there, I applied and was hired to join the trade mark department.

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

A journalist.

Which three words would you use to describe yourself ?

Dedicated, sociable, dynamic.

What was (were) your best subject(s) at school ?

Economics, Languages.

Complete the sentence : If I have time to myself

I would read more books and also travel more.

What is the best thing about your job ?

Apart from managing a team, practising in trade marks for a global portfolio gives me the opportunity to work in many diverse areas within my field of practice, and also to face many interesting challenges.

I also appreciate the opportunity to meet and work with different people from all over the world.

What did you want to be as a child ?

A veterinarian to take care of pets (I had a cat at that time).

What is your biggest regret ?

Not to have time enough to spend with my family and my friends.

What is your favourite work of art ?

Monet – Impression Sunrise.

What is the best age to be ?

I think there is no best age. It depends on how you feel.

What is your weakness ?

Chocolate and cakes.

Which book or books are you currently reading ?

Chess Story by Stefan Zweig.

What is your favourite children's book ?

The Little Prince by Antoine de Saint Exupéry.

How do you relax ?

Walking, listening to music, reading and when possible gardening.

What is your favourite drink ?

A glass of good red wine.

Do you have any unfulfilled ambitions ?

I would like to travel to Vietnam and South Africa.

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

The Eiffel Tower - of course - I am French. Its structure is so amazing and original. At night when it is lit, it is magical.

What's the best invention ever ?

Aviation in general – it is incredible how you can fly from one place to another so quickly.

Which modern convenience could you not live without ?

A mobile phone.

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