Law Lore & Practice

PTMG Pharmaceutical Trade Marks Group

Dec 2013

Editorial: A song for all seasons

During a recent BBC Radio 4 edition of Law in Action, the former Court of Appeal Judge, The Right Hon. Professor Sir Robin Jacob declared that copyright was a 19th century "tax on knowledge". He claimed that unlike Patents whose limited lifespan stimulates innovation, this other arm of intellectual property does nothing to encourage people to create or to better perform works of art. His interview was a response to the 2011 European Union Directive aligning performing rights with copyright. A challenging point of view which would certainly have found favour with Maurice Ravel, the French composer.

Ravel is the subject of a new play, based on the book of the last ten years of his life which is currently receiving excellent reviews here in Paris. Ravel is quoted as having been very disparaging to Paul Wittgenstein the Austrian one armed pianist, following a highly modified interpretation of the composer's piano concerto for left hand, commissioned by the pianist himself. The Austrian's defence (that the concerto needed improving) may possibly have found favour with performing arts' associations who understandably defend an entirely favourable view of the provisions contained within the Directive. Their support is particularly appreciated by session musicians who often find themselves facing delayed percentage payments from record companies rather than down payments for hours played.

Neither copyright nor any other intellectual property right was on my mind when, as a teenager, I like millions of others of my generation around the world, stayed up all night to watch Live Aid and a few years later in June 1988 the Nelson Mandela 70th Birthday Tribute. Performing artists at that stage in my political awakening were the vehicles for a strong message and we all believed at the time that our viewing had provided the much needed popular surge of public opinion which led to Mandela's release some twenty months later.

Listening this week to the many moving tributes, commentaries and memorial services about that extraordinary man, I am reminded that both those global events took place in a world before social media. Turning on the radio and watching the television were the only means available to take part in such momentous occasions. Not for us Twitter or Facebook but rather the reality of shared emotions the next morning at school.

Whichever artistic medium you chose, whether it be virtual or good old fashioned Christmas cards sent by snail mail, may you all be able to celebrate the holiday season in style!

Vanessa

US Law Update

James Thomas, Thomas Trademarks and Copyright Legal Services, USA

The US Court of Appeals for the Federal Circuit recently affirmed a decision of the US Trademark Trial and Appeal Board (TTAB) holding that PRASTERONE.ORG and THE PRASTERONE COMPANY were generic for the following services: "providing a website featuring scientific and clinical research information about investigation medical foods, dietary supplements or drugs, namely, prasterone or derivatives or analogs thereof." The applicant had filed applications to register these marks on the Supplemental Register, which is a register for descriptive marks that do not qualify for registration on the Principal Register, but otherwise are capable of distinguishing an applicant's goods or services, ordinarily through sufficient use. The Supplemental Register does not provide all the same advantages as the Principal Register, but it does allow a mark to be registered. If, however, a mark is found to be generic and thus incapable of distinguishing an applicant's goods or services regardless of the amount of use, then it will be refused registration on both the Principal and the Supplemental Registers. In this case, the Appeals Court agreed with the TTAB that these marks were generic for the identified services, concluding that the addition of generic terms such as .ORG and COMPANY did not alter the generic meaning of the marks. Thus, the Court affirmed the decision to refuse registration of these marks on the Supplemental Register.

In another recent decision, the TTAB found that the mark ACTRX for dietary and nutritional supplements, which the applicant stated will be sold only as prescription medicines, was confusingly similar to the prior mark ACT (and related marks) for an anti-cavity mouth rinse sold over-the-counter. In reaching this conclusion, the TTAB found that the RX element of the applicant's mark would be understood as referring to "a medical prescription" and was therefore a weak element of the mark. The TTAB further noted that even if non-prescription supplements were sold under the ACTRX mark, the RX element would have a suggestive connotation "indicating that the supplements are of a greater strength or efficacy, similar to that of a prescription product." The TTAB further concluded that even though the applicant's goods would be obtained at a prescription counter and the opposer's goods are sold over-the-counter, the same class of consumers, namely, the general public, would encounter both goods. Therefore, this difference did not eliminate the likelihood of confusion.

Words from the Chair

How can it possibly already be the end of the year? Christmas decorations have invaded the streets and shops of London and yet I feel as though it is still only September!

This is the final edition of LL&P in 2013 and I would like to take the opportunity of this short column to acknowledge the work of two people; Vanessa Parker, editor of LL&P and a long time PTMG Committee Member and James Thomas, founder and partner of Thomas Trademark & Copyright Legal Services. James has done a fantastic job of re-vamping the PTMG website and his on-going support in relation to this is invaluable.

From the PTMG Chair's point of view, one could not dream of a better editor than Vanessa. I am sure all our regular LL&P readers would agree with me that Vanessa does an amazing job and keeps us all interested with a variety of articles in LL&P from one issue to another.

So to both of them, I would like to offer not only my gratitude but also a big thank you from the PTMG Committee and all LL&P readers.

To all of you, your family and friends, I wish you a merry Christmas and a happy new year.

Sophie Bodet

German Case-law on use of trade marks for Pharmaceutical Products

Margret Knitter, SKW Schwarz

As soon as the grace period during which there is no obligation to put the mark to use has expired, it is important to indeed use trade marks in order to enforce them successfully. For this purpose, all of the goods or services registered must be put to genuine use. Alternatively, there must be proper reasons for non-use to avoid the legal consequences of non-use, which may lead to cancellation of the trade mark in the worst case.

Trade marks for medical products are regularly registered under the heading of pharmaceutical preparations in accordance with the Nice Classification. They are commonly used for only one specific indication, however. Thus the question arises whether the trade mark owner is restricted to only this one specific product in its particular composition, prescription status, etc or whether he can be granted the broader extent of protection of the Nice Classification class heading. The German Federal Patent Court is steering a middle course on this matter. Where pharmaceutical marks are concerned, it uses the general indications of a list of medicinal products that groups pharmaceutical goods under 88 headings (groups of indications or active substances) in Germany (ROTE LISTE - Red List).

One example: the trade mark Babix has been registered for pharmaceutical preparations and is used for a drug to treat respiratory diseases with thick phlegm. According to the Red List, this drug is to be grouped under heading 24 of antitussives/expectorants. The German Federal Patent Court held that the trade mark was used in a way that rights were preserved for antitussives/expectorants, but not for any additional goods under the general indication of pharmaceutical preparations.

In principle, a trade mark must be used in the form in which it was registered. Differences that leave the distinctive character of the trade mark unchanged however, have no prejudicial effect under Section 26(3) German Trade Mark Act. Differences without prejudicial effect are to be presumed where the relevant public will perceive the registered and used forms as the same trade mark from their overall impressions.

It is often difficult to judge the addition of new elements to the trade mark. If another distinctive element is added to the sign, it will often change the distinctive character of the mark.

The German Federal Patent Court therefore denied that rights were preserved by using the trade mark TIMOPTOL in the form of CHIBRO-TIMOPTOL. The Court held that CHIBRO-TIMOPTOL were two words of equal distinctiveness standing next to each other, connected by a hyphen. The relevant public would not consider this the use of a principal and a secondary brand, so that the distinctive character of the trade mark had been changed.

In another case The German Supreme Court denied that rights were preserved by using the word mark PROTI by use of designs.

The relevant public would regard the form of use as PROTI 4-K as one uniform sign rather than as two signs made up of the components PROTI and 4-K The same applies to the used form of PROTIPLEX. This would not be changed by adding the symbol ® after PROTI"since due to the graphic representation, the relevant public would consider the symbol ® as part of the form used in its entirety. If however, the relevant public were to regard the forms used to be one uniform sign, the distinctive character of the trade mark PROTI would be changed by the additions 4-K and PLEX, because these were not merely descriptive.

If the symbol ® is added to a two-word trade mark, this does not change the distinctive character, in accordance with case-law. Therefore the German Federal Patent Court considered it as having no prejudicial consequences that the trade mark Diclac dolo was used as Diclac® Dolo. There would be no indications that merely Diclac, but not Diclac dolo was understood as a trade mark. This all the more since the symbol ® had no distinctive character, but was rather an indication independent of the trade mark.

The same applies to the addition of merely descriptive and thus separable indications, such as extra, forte, etc. Accordingly, the German Federal Patent Court held that the used form of GYNODIAN® Depot was sufficient to preserve the rights of the trade mark GYNODIAN. The addition Depot was held to be an indication to a pharmaceutical preparation, which – if administered once – was active for prolonged release and effect periods, and was thus a merely descriptive indication.

Comment

The addition of merely descriptive signs usually has no prejudicial consequences for maintaining a trade mark. It should be made sure, however, that the trade mark is not blended into a unity with the addition, which would change the trade mark's character. In this event, it can still be denied that the trade mark owner used the trade mark in a manner as to preserve his rights.

Compulsory Licensing in India – An Inconvenient Reality

Mr. Ashwin Julka (Managing Partner) and Mr. Pankaj Soni (Partner), Remfry & Sagar

In the past 18 months if there is one issue that has divided intellectual property intelligentsia the world over, it is the compulsory license granted in favour of Natco Pharma to commercially exploit Bayer's patent on the cancer drug Nexavar (the Nexavar decision). The decision, as one reporter put it, set off a tidal wave of reactions. While on the one hand it was cheered by many as a step in the right direction to make medicines affordable to those who need them the most, innovator drug companies felt the ground beneath them shake and upped their cry of anti-innovation IP policies in India. But, whichever side you are on – and we urge you to walk the middle path before attempting to take sides – the real issue is to accept that compulsory licensing is an inconvenient reality in India. It is not a catastrophe as many believe; and our challenge lies in identifying the gaps that have been exposed in light of the Nexavar decision.

Much has been written and discussed about most, if not all, of the following questions. Is the deprivation of Bayer's (read innovator drug companies) right to exclude Natco (read generics) from commercially exploiting its invention the new trend of times to come in India? Is India really ready to walk down the compulsory licensing path because of genuine public interest or is it simply a tool for protecting the generics industry? Is compulsory licensing the work around that India has found to make sure that its patent laws are both TRIPS compliant and pro-generics? Or is it all much ado about nothing?

The key learning for innovator companies from discussions on any of the above questions is that compulsory licensing is here to stay, perhaps a rose that has its thorns, which, nevertheless, must be dealt with and businesses must manage to accommodate its challenges. Moreover, threats rarely, if ever, will work with a socialist democracy like India. Invite us to speak to foreign lawmakers and it will only reveal that the change being advocated is not collaborative but rather one being forced upon India. Talk to us as equals and you may be surprised!

India on the other hand must not gloat in this victory for its 20,000 plus registered pharmaceutical companies. We must understand and recognize that compulsory licensing is an exceptional tool, to be used as such, and that the underlying issue may be related more to the structural inadequacies of India's health care system, than to affordable medicines. Policy makers should appreciate that any pharmaceutical company – innovator or generic – is in the business to make money; hence the burden of affordable medicines and health care is not theirs to shoulder. There are other (better) alternatives which will solve our health care deficit, and if done well, will dilute any undue reliance on a compulsory licensing regime.

With the Nexavar decision presently on appeal with the Bombay High Court we will get further clarification on the legal aspects of the matter sometime in 2014. However, early indications, after the initial brouhaha, are that India will give compulsory licensing its due importance, but is willing to level the playing field by reducing the possibility of compulsory licensing being used as a tool to bypass business negotiations. The first compulsory license arrow, the Nexavar decision, hit bulls-eye, but the second and third lend hope. Though it may be too early to take a call, it seems that the second arrow is fluttering towards a miss or a partial hit at best. In early 2013, the Health Ministry in India recommended to the department of industrial policy and promotion, compulsory licenses for three anti-cancer drugs – Roche's Herceptin and Bristol-Myers Squibb's Sprycel (Dasatanib) and Ixabepilone. However, none have issued so far, which goes to show that India is not trigger happy when it comes to granting compulsory licenses for medicines. But, stay tuned to see where this one ends up.

As if taking a cue from the Health Ministry's recommendations, BDR Pharmaceuticals International Pvt. Ltd. fired the third arrow, seeking a compulsory license for Dasatanib (used to treat a certain type of chronic myeloid leukemia). But that request has recently been rejected. In the Dasatanib decision, India's Controller General of Patents rejected BDR Pharma's request because, in his opinion, voluntary licensing discussions were inadequate. Frowning upon BDR Pharma's reluctance in pursuing licensing discussions in a proper business context, the Controller General, perhaps, saw the compulsory licensing application as a strategy to circumvent business negotiations and to let the provisions of the patent statute strong-arm the licensing process. According to the Controller General, effort (as also required under Section 84(6) of the Patents Act, 1970) in negotiating a voluntary license must be diligent and a compulsory license application cannot be otherwise used to bypass this procedure. Thus, the third arrow missed its target with a well reasoned outcome that reinforced the importance of plain, old fashioned business dealings. Simply put, if the Nexavar decision forced innovators to talk to generics with diligence and seriousness, the Dasatanib decision requires generics to do the same.

Looking from the glass half-full point of view, the take away here, apart from the fact that an informed un-biased opinion is the call of the day, is that all is not lost for innovators. India is perhaps doing what others have done (or will do – which is the real fear) but India is also willing to understand the ramifications of a badly managed compulsory licensing regime. The solution lies in the middle and time will tell if we get there sooner rather than later – or get there at all.

International Update

Czech Republic

PETOSEVIC

The customs officials in the Czech Republic have recently seized a total of 194,300 counterfeit Viagra and Cialis pills at Prague's Vaclav Havel airport.

The fake anti-impotence pills originated in south Asia. The investigation is ongoing and it is not yet known whether they were intended for the Czech Republic market.

If sold as originals, the estimated value of the pills would have been EUR € 3.4 million (USD $ 4.6 million).

India

Sonal Madan, Chadha & Chadha

In a recent judgment in Bloomberg Finance LP v Prafull Saklecha dated 23 October, 2013, the Delhi High Court while restraining the Defendants from using BLOOMBERG as part of their corporate name has thrown light on the provisions of dilution as envisaged in the Indian Trade Marks Law.

The decision comes at an opportune time given that the legal position on unauthorized use of a registered mark as part of corporate name by a third person in respect of goods/ services which are different from those covered by such registration was ambiguous. The precedents relied upon by the Defendants limited the scope of infringement provisions to use of a registered mark as a corporate name in respect of the same goods and services as covered by such registration.

The Court was of the view that the element of having to demonstrate the likelihood of confusion is absent from the law on dilution and thus restrained the Defendants from using the Plaintiff's registered trade mark BLOOMBERG as part of their corporate name despite the fact that the two parties were involved in completely different businesses. The court further clarified that a trademark with a reputation shall be entitled to anti dilution protection even if it cannot be said to be well known.

The decision is particularly good for the Pharmaceutical industry as their marks having reputation cannot be used in different industries.

Moldova

Nicolae Muresan, Andra Musatescu Law & Industrial Property Offices

EGIS Gyogyszergyar Nyilvanosan Mukodo Reszvenytarsasag (EGIS), has just obtained a positive decision from the Moldavian Trade mark Office (AGEPI).

Facts of the case:

AGEPI issued a provisional refusal for the international trade mark ALTFORALLE, which was considered by the Trade mark Office as similar with ALTORAL and ALTORAL (in cyrillic) trade marks registered for 'antiallergic pharmaceutical products', as ground for refusal.

EGIS filed an appeal against AGEPI's Provisional Refusal.

Arguments:

Our main arguments were based on the following:

(1) ALTFORALLE cannot be considered similar with ALTORAL taking into consideration (i) the difference in size between the two trade marks, (ii) the inexistence of semantic similarity between the examined trade marks taking into account that none of the trade marks has a meaning, (iii) the doubling of the letter 'L' puts the emphasis on the ending of the word;

(2) in order to even further depart from any potential similarity of products, EGIS decided to limit its products from 'pharmaceutical preparations for human use' to 'pharmaceutical preparations for gynaecological use';

(3) 'pharmaceutical preparations for gynaecological use' cannot be considered similar with 'antiallergic pharmaceutical products';

(4) there is no likelihood of confusion including association;

(5) only Moldova issued a provisional refusal on such grounds.

Findings of the Trademark Office:

Further to the arguments brought before it, the Office issued a final decision in favour of EGIS, overturning its provisional refusal.

Comments:

We consider the final decision of the Trade Mark Office, which was summoned to us on 31 October, 2013, as well founded and of importance, not only for EGIS, which is now able to use the same trade mark in all of the countries where the protection was requested (e.g. Poland, Czech Republic, Romania, Bulgaria etc.) via the international registration, but also as a precedent. In this respect, our view is that AGEPI will take this decision into account in future similar cases.

Ukraine

PETOSEVIC

On 7 August, 2013, the Simferopol District Court, in the southern Crimea region of Ukraine, imposed fines to the amount of approximately EUR € 3,000 (USD $ 4,000) on two members and a fine of EUR € 3,600 (USD $ 4,900) on the leader of an organized group that produced and sold counterfeit water softener Calgon. In addition to imposing fines, the court prohibited the three defendants from engaging in business activities for two years.

Since the fall of 2005, the defendants manufactured the fake water softener in a rented apartment in Simferopol by mixing a fabric dye called Sinjka and laundry powder called Lotos, produced in Ukraine. They used polymer film and a heat gun to make the packaging. During the search of the premises in 2007, more than 14,000 counterfeit packages of water softener weighing half a kilo each were found and seized.

The request for compensation of material damages in the amount of EUR € 68,000 (USD $ 92,000) filed by the trade mark owner Reckitt Benckiser Household and Healthcare Ukraine was partially sustained by the court, which awarded compensation in the amount of approximately EUR € 2,300 (USD $ 3,100).

Members News

New Members

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

Elena Zuykova of Zuykov & Partners, Moscow, Russia info@zuykov.ru

Halim Shehadeh of Cedar White Bradley, Dubai, UAE halim.shehadeh@cedarwhite.com

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Moves and Mergers

Stefano Marino has left Sigma-Tau in Italy to join the European Medicines Agency in London as Head of Legal Department

Alma Alvarez y Delucio and **Israel Hernandez** have left Alvarez Delucio Y Associados and established Breakthrough IP Intelligence SC in Mexico City. They can now be reached at alma@breakthroughip.com and Israel@breakthroughip.com

Gerard-Gabriel Lamoureux has left Cabinet Hirsch and can now be contacted at gerard@lamoureux.pro

Traugott Fischer has left Acino Pharma AG and is now practising under his own name. Traugott can be contacted at traugott.fischer@gmx.ch

Alexander Miller has left IP Solutions in Liechtenstein and is now practising under his own name in Switzerland. Alexander can be contacted at info@miller-legal.ch

Isabelle Leroux and **Denis Voevodin** can now be reached at isabelle.leroux@dentons.com and denis.voevodin@dentons.com following the recent merger of Salans into the Dentons Group

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

PTMG Autumn Conference Report

Vienna 2nd 4th October 2013 - Barriers to a global brand

Sarah Jeffery, GSK & Vanessa Parker, PTMG

Some 430 delegates flew into Vienna in early October from all corners of the globe for the 87th PTMG conference.

After a bustling welcome reception on the Wednesday evening followed by various parties around the city an emphatic breakfast gong drew the last few sleepy heads into day one of a packed agenda. In her welcome address our chairman Sophie Bodet noted the record number of delegates and that registration had closed early. She also commented on both the new look LL&P and PTMG website and thanked Vanessa Parker, Sean Brosnan and James Thomas for their efforts. It is no surprise that PTMG continues to go from strength to strength, for those of us in the pharma industry and those who work for pharma clients the presentations are the most relevant and the networking the most fruitful of any conference offering.

Christina Scobie & Derek Rossitter

The now traditional Founder's Lecture, created to honour and celebrate our founder Derek Rossitter who was in attendance, was presented by Christina Scobie from Merck who provided an eloquent introduction to the conference and its theme of challenges to a global brand. She outlined the great difficulties that we all face from the clutter of class 5 to the 40-50% attrition rate during clearance as well as the ongoing regulatory hurdle. She concluded that whatever we do, it is the safety of our patients that is paramount. Derek Rossiter gave a very touching and amusing response congratulating Christina both on her speech and for fielding some tricky questions. He reminisced of his time during Second World War when he found himself thinking it would be better to work together to agree rather than to fight it out. The fact it took until 1968 for the first meeting to be held in London with 7 people present caused Derek to describe himself as "a gigantic great fraud" which I am sure no one would agree with. From this rousing beginning we were launched straight into the complex but riveting topic of Local Language as a Barrier to a Global Brand courtesy of

Andreas Popper

Andreas Popper from Naexas Compass Group. Andreas' impressive grasp of multiple languages places him in the privileged position of understanding not only a language itself but also how languages work and in particular those with foreign alphabets that require the filing of transliterations. We are now all more familiar with the concept of pictorial meanings and syllabaries as opposed to plain old letters and words! So many companies create transliterations on a country by country basis without exploring whether there could be a regional possibility. This particularly applies to Asia where although a pictorial mark may be pronounced differently in different countries, it could still be understood from the images in various countries.
Frances Drummond of Norton Rose

Frances Drummond

Australia & Catherine Boudot of Biofarma provided the audience with an overview of the various updates to the plain packaging situation that have arisen since the last PTMG meeting highlighting Australia's blazing trail in relation to tobacco legislation. Many countries have been keenly observing progress in Australia so we can't view this as a one country only phenomenon. Frances also scared a lot of brand owners when she used various mock up scenarios of how our OTC packaging might look if the Therapeutic Goods Administration (TGA) labelling and

Catherine Boudot

packaging proposals go ahead, including the generic name taking greater prominence than brand or even that the company logo may not be allowed to appear on packaging. Catherine offered us an overview of the direction that is being taken in the EU and US. One particular concern is that packaging is part of the Marketing Authorisation and is therefore submitted in the dossier. If packaging changes and becomes non compliant, the MA could therefore be suspended. In the US recommendations arising from various consultations included discouraging the use of logos, bars, stripes, symbols and also to "avoid or minimise the use of corporate trade dress". PhRMA are apparently exploring a potential claim that recommendations may breach first amendment right to freedom of speech. We were all encouraged to engage with the ongoing government consultations in Australia whilst we have the opportunity and to work as an industry to assist in lobbying efforts.
After a refresh and a chat during the coffee break and more of the hotel's

Joelle Sanit-Hugot

unique savoury lollipops with bows, Joelle Sanit-Hugot of Sanofi gave us an expert tour of the new guidelines that were issued in June 2013 by the EMA Name Review Group (NRG) whose role is to review proposed pharmaceutical trade names prior to approval by the CHMP. Two of the major changes included

the fact that the NRG now wants exclusive use of electronic submission and that the number of NRG meetings per year has been halved (current response time is 3 months). There is presently a large NRG database of approved names, the majority of which, have never been used. Industry have successfully worked together to suggest to the EMA ways of cleaning the database resulting in the introduction of a 3 year limit on acceptance of the intended name. Remaining on the topic of regulatory practice in relation to the

Susan Keri

approval of trade mark candidates, Susan Keri of Bereskin & Parr offered us a vibrant insight into recent and proposed changes to Health Canada guidance. Several areas remain unclear, for example what information must be contained in submission with respect to brand name. It seems as though with all the regulatory authorities, the biggest challenge that brand owners face is that of uncertainty or lack of transparency over the process. In Canada, like many countries, name submissions are confidential and current rejection levels are not tracked or public thereby making the process challenging for applicants. We look forward to hearing more from Canada in the near future as a final version is expected any time from-now through the first quarter of 2014.

Susan Proulx

Susan Proulx of Med ERRS joined the stage to reflect on the US position. Whilst the new risk assessment guidance was released in December 2012 (relating to data collection, potential error scenarios etc.) and Package & Label guidance in April 2013, the pharma trade mark community are still waiting with baited breath for the Nomenclature Draft guidance which is delayed in part as a result of the ongoing government shutdown that coincided with the conference. The FDA is often considered to be one of the most strict regulatory regimes and, as Susan joked, sometimes it seems that the FDA use a "Murphys law" approach i.e., assuming that if anything can go wrong it will! Susan also offered an overview of the December 2011 Medicines Control Council guidance from South Africa, one of the most surprising facts being that the MCC review candidate marks in 11 languages. Overall the current regulatory environment leaves us with more questions than answers. What struck me is the wide variety of differences between those countries that have highly developed naming processes for medicines. It is definitely a concern that as more countries further develop their regulatory systems, we as trade mark lawyers may have more and more hurdles to jump over leading to ever increasing costs. As many of the regulatory speakers highlighted this is likely to lead to the need to start name creation a little earlier,

Frank Meixner

or to consider a "name bank" and also raises questions around filing strategy: US first due to rejections? Or Canada first due to most comprehensive evaluation? Or might the EU have a better chance of approval? On this sombre but thought provoking note we finished the day's more formal presentations looking forward to a more light hearted evening ahead.
Departing on coaches into the surprisingly crisp and chilly Viennese air whisked at twilight through mist tinged vineyards to Gumpoldskirchen some 30km outside Vienna where an old world cobbled town lies at foot of hills to be welcomed by a traditional brass oompah band and restorative glasses of schnapps. After a reception we were led by the band through the streets to a restaurant which was a veritable rabbit's warren of smaller rooms swallowing our large group up. We were treated to an evening of typical Austrian food including meats, sauerkraut, dumplings and strudel. After a display of folk dancing our carriages whisked us back to Vienna to conclude a long but fruitful day.
Our second full day began with a lively presentation from PTMG committee member Frank Meixner of Bayer on the

Stuart Hurst

topic of Coexistence and Prior Rights Agreements. Many of us routinely use such agreements; however we rarely discuss the varying legal ramifications in different jurisdictions of what are often template agreements. To those outside of the day to day vagaries of the pharma industry it will likely come as a surprise that an estimated 50% of class 5 applications involve some form of co existence. The fact that very few court precedents can be found involving such agreements highlights their success.
What is clear is that there are significant differences between what is and isn't permissible between Member States and the US. For example in both France and Germany an agreement can only be limited to the territory of the current conflict whereas UK law is not as strict and arguably does permit global agreements (Apple v Apple). There are also other areas of the law to take into account, in particular restraint of trade considerations. I certainly came away questioning my approach to such agreements and will revisit practical considerations.
It is always nice to have a non-legal perspective in the mix of presentations which was provided by Stuart Hurst (formerly of Pfizer and Eli Lilly & now a public affairs consultant). He offered an overview of the implications of the Falsified Medicines Directive in the EU. Sadly the business of counterfeit medicines is increasingly attractive to criminals. It is particularly shocking to hear that the profit margin for fake Viagra is 200% greater than for cocaine. The FMD focuses on standardisation of the legal supply chain and involves measures at all stages from manufacturing of APIs through to the distribution chain and ultimately patient dispensation via the use of serialisation to enable verification. There is however a need to try and standardise systems between countries to ensure pharma companies aren't left having to incorporate 28 different serialisation systems into their packaging. This will take time, in fact it is expected that serialisation and verification systems will begin implementation between 2014-2017.
After the coffee break, we were whisked off to the African continent for a joint presentation by Sarah Jeffery of GSK and Chris Walters from Spoor & Fisher.

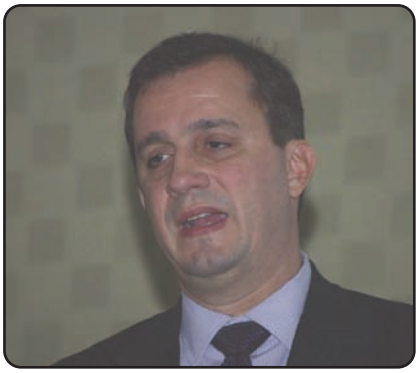
Sarah Jeffery & Chris Walters

Between them, they certainly provided a comprehensive overview of the opportunities and challenges of this wide variety of jurisdictions with varying legal systems. Delegates were particularly impressed with the wealth of experience shared by Sarah who gave us first hand examples of anti-counterfeiting strategies and enforcement in specific countries. Her comment that actions taken in these markets ensure that genuine medicines reach "the people who need it most" was a timely reminder. By the end of this session, Sarah's passion for Africa had become infectious and provided many with food for thought over lunch.

The last presentation of the conference was a panel presentation chaired by PTMG committee member Marcus Goldbach on the topic of the Madrid

Marcus Goldbach & Carlos Polo

Protocol and proved to be a very lively, rousing conclusion to the seminar schedule. Carlos Polo of Carlos Polo & Asociados offered an extremely spirited introduction to the Madrid Protocol and WIPO filing system. Should anyone have accidentally dozed off after a large Friday lunch they would not have remained asleep for long due to the number of



Alvaro Loureiro Oliveria

musical interludes and films Carlos deployed. Alvaro Loureiro Oliveria of Dannemann Siemsen gave a very positive update on implementation in Brazil including the news that 90 new examiners have been appointed and that by 2015 it

Maury Tepper

should only take 9 months from filing to registration; good news indeed! Maury Tepper from Tepper & Eyster did a fantastic job of stepping in at the last minute to present on the US relationship with the Madrid system, I have to admit I hadn't realised how close the US WIPO negotiations came to being derailed by some Cuban rum!

All of the presenters did an excellent job and I thoroughly recommend accessing their presentations whilst they are still online on the PTMG website. I also thought that the conference organisers

A committee member in traditional costume

ran a very slick operation meeting all the delegate's needs. No PTMG conference is complete without a gala dinner on the last night and Vienna was no exception. A sparkling reception was followed by three courses of delicious food before a good proportion of the conference danced the night away to the banging sounds of the DJ's Europop, some more enthusiastically than others!

One of the many things that struck me during the course of our Vienna meeting was the incredible number of acronyms we all used during the presentations which made me think that perhaps we should have a Christmas quiz. No prizes I'm afraid, just basking in the glory of knowing you're an acronym ace!

Vienna Acronym Quiz !

DMEPA:

Division of Medication Error Prevention and Analysis (US FDA committee who consider trade mark candidates)

MCC:

Medicines Control Council (regulatory authority of South Africa)

CHMP:

Committee for Medicinal Products for Human Use (EU regulatory approval body)

EFPIA:

European Federation of Pharmaceutical Industries and Associations

TGA:

Therapeutic Goods Administration (Australian regulatory authority)

INN:

International Non-proprietary Name

MAH:

Marketing Authorisation Holder

DTC:

Direct to consumer

COFEPRIS:

Comisión Federal para la Protección contra Riesgos Sanitarios (Mexican regulatory authority)

FMD:

Falsified Medicines Directive

API:

Active Pharmaceutical Ingredient

GMP:

Good manufacturing practice

Clinical trials – genuine use or legitimate excuse?

Frédérique Potin and Adrian Smith, Simmons & Simmons

As raised at the last PTMG conference in Vienna, recurring questions which pharmaceutical companies encounter in relation to the maintenance of their trade marks are whether use of a trade mark in clinical trials, before the product is actually put on the market, constitutes genuine use or whether the necessity for a product to undergo such trials may amount to a proper reason which excuses non-use of the mark. In jurisdictions such as US and Canada, this question will also arise at the stage of the trade mark application, where the applicant must establish use or intent to use, notwithstanding that the product is still under the clinical trial process.

With such a high percentage of trade marks being rejected by the authorities charged with approving the naming of pharmaceutical products, it is crucial to ensure that, once a trade mark has been accepted for a particular product, it achieves protection and such protection is maintained.

Following a brief review of the position in the European Union, certain Asian territories, US and Canada, it would appear that not all jurisdictions take the same approach.

European Union

In the EU it appears that use of a trade mark in connection with clinical trials will not generally be considered as "genuine use" of the trade mark as seen in the Opposition division decision No 421/1999 dated 01 July 1999, Mucos v Genzyme. However, the fact that the placing of the product on the market under the mark is delayed due to the requirement for the trials may amount to a "proper reason for non-use" (under Article 12 of Trademark Directive 2008/95, "a trade mark shall be liable to revocation if […] it has not been put to genuine use […], and there are no proper reasons for non-use").
This approach is based on Article 19 (1) of the TRIPS' agreement which provides that: "If use is required to maintain a registration, the registration may be cancelled only after an uninterrupted period of at least three years of non-use, unless valid reasons based on the existence of obstacles to such use are shown by the trade mark owner. Circumstances arising independently of the will of the owner of the trade mark which constitute an obstacle to the use of the trade mark, such as import restrictions or other government requirements for goods or services protected by the trade mark, shall be recognized as valid reason for non-use".
As will be apparent from the above, TRIPS specifies that only situations arising independently of the trade mark proprietor may constitute valid reasons for non-use. In this respect, clinical trials and other processes related to marketing authorization, being requirements imposed on the trade mark proprietor by regulation, should be considered as circumstances independent of the trade mark proprietor.
However, it appears from OHIM's decisions and the approach of certain national courts in member states, that clinical trials will be recognized as "proper reasons for non-use", only if the trade mark proprietor is able to establish that it has been active in seeking to progress the clinical trial process.

Indeed, the evidence which will enable a proprietor to successfully claim valid justification for non-use of a mark as a result of clinical trials remains a concern, as evidenced by OHIM's approach to this issue. For instance, as early as 1999 in the above cited case, OHIM considered that the fact that only one document was produced, establishing that clinical trials were under way, with no indication of what had occurred since the trials were commenced, or whether they were still pending, did not show a valid excuse for non-use of the mark.

Nearly 15 years later, OHIM's position appears to remain the same. Indeed, in the 25 April 2013 Opposition Division decision in the Onyx Pharmaceuticals, Inc. v Alimirall SA case (which has now been appealed), the opponent was asked to produce proof of use of the earlier mark on which the opposition was based. The opponent produced various documents evidencing that clinical trials had been requested for a particular medicine in various EU countries, that authorizations to conduct the trials were granted and that it had also attended various exhibitions. However, as the clinical trials were conducted before obtaining a marketing authorization, none of the documents explicitly referred to the trade mark in dispute.

The Opposition division considered that the documentation was not sufficient to reveal the opponent's intention to use the trade mark in relation with the product as such documentation only referred to the active molecule. It concluded that such documentation was insufficient to prove that the earlier trade mark was put to genuine use during the relevant period. Upon review of this decision, although the opposition division appears (confusingly) to have switched from an analysis of valid reasons for non-use to an analysis of proof of genuine use, it appears to confirm that the mere existence of on-going clinical trials may not be sufficient to constitute a valid excuse for non-use and that the trade mark proprietor must be prepared to demonstrate its active behaviour in relation to the clinical trials, in pursuit of bringing the product to the market under the trade mark.

At national level too, relying on clinical trials to establish valid reason for non-use may not be sufficient. For instance, in the German case GRUR, 1999, 1002 – SAPEN II, the Federal Patent Court denied a justification of non-use of a 25 year old trade mark registration, as the proprietor was deemed not have seriously progressed the two product registration proceedings initiated during the 25 year period.

In France, the approach appears more straightforward, as existing case-law does not show any particular difficulties for trade mark proprietors to establish valid reasons for non-use, provided that they can demonstrate that a clinical trial or a request for a marketing authorization is on-going. This position is upheld by past decisions such as Paris Court of First Instance 01 June 1999 SA Almonda Sociedade Gestora de participacoes Sociais v Opfermann Arzneimittel GmbH and Orleans Court of Appeal, 13 Fegbruary 2003, A. Deschamps v SA Mermet

Outside the European Union

If we look at the position outside the EU, it appears that Japan, China and Hong Kong, broadly speaking, share the EU approach i.e., other than post-marketing trials or in other exceptional circumstances, use of a mark in connection with clinical trials does not constitute genuine use of a trade mark, but may be accepted as a valid excuse for non-use.

In US and Canada, where the question of use of a trade mark arises at the stage of the trade mark application, we understand that it is generally accepted that use of a trade mark during clinical trials will constitute sufficient use to file an application, as clinical trials are part of pharmaceutical companies' "ordinary business". This approach will, however, only be relevant when the mark is actually used on the product, which appears likely only to be the case in the later phase clinical trials.

In view of this, filing a declaration of actual use or trying to support use in a non-use cancellation action on the basis of clinical trials may be difficult in both US and Canada and, consequently, a trade mark application based on use is probably only viable in later phase clinical trials, if and to the extent that the trade mark applied for is marked on the product.

Summary

To summarize, it would appear that clinical trials are capable of being accepted as providing proper reasons for non-use of a mark. Trade mark proprietors must however be prepared to ensure that the evidence filed clearly establishes their active engagement in the trials and their intention to use the trade mark once such trials have been completed. Clinical trials may be accepted as genuine use only in certain countries, such as North America, and where the trial is in its late stages.

Australian Self Medication Industry Social (ASMI) Media Guidelines

Bernard O'Shea, Frances Drummond, Norton Rose Fulbright Australia

In November 2013, the Australian Self Medication Industry (ASMI) became the first healthcare industry body to release social media guidelines (the Guidelines). ASMI is the peak industry body for the Australian self-care industry, representing consumer healthcare products including over the counter and complementary medicines.

The Guidelines apply to non-prescription medicines and aim to provide practical guidance as to how social media can be used in this sector, while still ensuring compliance with professional, ethical and regulatory obligations. ASMI worked with Weber Shandwick, a communication agency, to develop the guidelines.

Social media is already a vital communications channel in commerce and the healthcare industry is no exception. Filomena Maiese, ASMI Marketing and Business Development Director emphasised this point, stating that "80 per cent of people [go] online first for health information". In an increasingly 'instant' world, organisations which do not provide instant information run the risk of falling behind as the nature and speed at which organisations and consumers interact evolve.

Despite this, the industry has been quite cautious in embracing social media sites such as Facebook and Twitter, as the healthcare space in Australia is so highly regulated, leading to much uncertainty about what is and is not acceptable social media content. The intention of the Guidelines is to provide ASMI members in particular more certainty, "increasing their confidence in connecting brands and health information with social media audiences in a compliant and responsible manner."

The Guidelines are intended as a broad guide only, and are not intended to replace or alter an organisation's obligations under any relevant code of conduct, regulation or legislation. Rather, the purpose of the Guidelines is to assist organisations to meet their existing obligations.

The Guidelines provide a necessarily broad definition of social media, in order to capture new forms of social media that have not yet been contemplated. Social media is characterised as a subset of digital media. It is also defined as any online channel that can provide a 2-way interaction between two parties. Facebook, Twitter, YouTube and LinkedIn are clear examples, but this also extends to user review sites, blogs, forums and message boards. Social media is further characterised as an eco-system of owned, earned and paid media.

Owned media includes "any online profile, channel or forum where the organisation can exhibit some level of control over its content", such as a Facebook page or Twitter profile. This is contrasted with earned media, such as Twitter public replies, individual Facebook accounts or articles on mainstream news websites, where there is no direct control or influence by the organisation. Paid media is "any piece of media (comments, photos, advertisements) that has been sponsored and or paid for by the organisation", such as Facebook ads or sponsored Tweets. Owned media and paid media are treated as advertising.

The Guidelines go on to list some of the issues which may arise for an organisation in operating social media, including false or misleading claims, copyright infringement, defamation, breaches of confidentiality and breaches of privacy, however these issues are not dealt with in detail. The Guidelines also remind organisations that additional obligations apply where therapeutic goods are concerned, such as advertising requirements specific to therapeutic goods, and adverse events.

An important point to note is that these issues can apply whether the organisation is the author of the content or not. While managing owned content is somewhat easier as the organisation has control over what is published, the Guidelines provide that any comment or post made by a user on such owned content (i.e. a post on an organisation's Facebook page) is also the organisation's responsibility, and "any comment in breach of any requirement should be removed within a reasonable time" of the organisation becoming aware of it. ASMI suggests that a reasonable time frame is 24 hours for large companies and one week for Small to Medium Enterprises. The obligations in relation to owned media also apply to paid media.

The Guidelines acknowledge that organisations have no control over content in earned media and that monitoring of such social media is not mandatory, however it is becoming increasingly common practice to do so. If, via monitoring of content in earned media, the organisation (or any agency monitoring on behalf of the organisation) becomes aware of content in breach of any legal requirements, the Guidelines provide that the organisation should take all reasonable steps to correct that material, noting that the organisation will itself be unable to take down any earned media content as it is not controlled indirectly or directly by the organisation. If the organisation or agency becomes aware of an adverse event, the organisation or agency must report such adverse event as soon as they are made aware of it.

The Guidelines also provide that it is up to the organisation to keep up to date with new forms of social media and to ensure that "campaigns and consumer engagement is ethical and executed to best practice". Further, if an organisation publishes a link to a third party or owned media site, the organisation must also monitor the site that has been linked to (including assessing the compliance of that linked site to the relevant codes and legislation). This could be quite onerous. It is therefore an important consideration if an organisation is contemplating placing links to other parties' social media sites. The Guidelines do however indicate that the organisation could get around this obligation by notifying the consumer (by way of pop up alert, for example) that they are leaving the company controlled site.

The Guidelines are in a way quite narrow in scope. The main focus is on what is social media, and how social media can be categorised, and are limited to non-prescription medicines. The recommendations are quite broad and provide little in the way of real life examples to assist organisations. However, while the Guidelines are in some ways quite limited, ASMI is the first industry body to publish any guidelines in this space. Acknowledging the pervasive nature of social media is an important first step and it is likely only time before other industry bodies begin releasing their own social media policies and guidelines that will have a broader application across the industry.

The Alicante Torpedo: change in practice when enforcing CTMs and RCDs

David Stone and James Fox, Simmons & Simmons

A recent series of cases has led to a change in practice when seeking to enforce European Union wide registered rights. Previously, a letter before action was usual, prior to commencing proceedings. That has now shifted, with practitioners filing (but not serving) proceedings before contacting the alleged infringer, to prevent a 10 year stay of the infringement proceedings.
So what is the "Alicante Torpedo" and will it apply in the pharmaceutical industry?

Background

Where invalidity proceedings have already been commenced before the Office for the Harmonization of the Internal Market (OHIM) or another Community court, article 104(1) of the Community Trade Mark Regulation (CTMR) and its sister provision article 91(1) of the Designs Regulation require a stay of any Community Trade Mark (CTM) or Registered Community Design (RCD) infringement proceedings in order to avoid inconsistent decisions on the validity of EU-wide rights. However, the infringement court, even if second-seized, may continue to hear the action if there are "special grounds" for doing so. These provisions only apply if the invalidity action has been filed before the infringement action. If a defendant wishes to challenge the validity of an EU-wide right after it has been sued for infringement, the appropriate venue is the infringement court by way of a counterclaim for invalidity.

BSkyB

The Court of Appeal of England and Wales considered the issue of special grounds in relation to article 104(1) of the CTM Regulation in the joined cases of EMI and Starbucks v BSkyB. The cases arose as a result of BSkyB's proposed launch of an online TV service under the name NOW TV. Having received cease and desist letters from both EMI and Starbucks, BSkyB commenced proceedings before OHIM to invalidate the CTMs relied on by EMI and Starbucks. When EMI and Starbucks then sued for trade mark infringement and passing off before the High Court in London (sitting as a Community trade mark court), BskyB sought a stay of the infringement proceedings on the basis that OHIM was first-seized, and there were no special grounds. The Court of Appeal espoused the following principles regarding special grounds, applicable to both CTMs and RCDs:

- The presumption in favour of a stay is a strong one;
- It will be "a rare and exceptional case" where special grounds are established;
- It is irrelevant that the parties have reached agreement between themselves;
- Special grounds must relate to factual circumstances specific to the case;
- It is irrelevant that OHIM proceedings take up to 10 years. Specific facts giving rise to particular urgency may, depending on the circumstances, constitute special grounds, but the urgency must be so great as to over come the heavy presumption in favour of the stay – "[t]he general need of business to know where it stands is plainly not sufficient";
- The fact that the defendant ran to OHIM after receiving a cease and desist letter is irrelevant in establishing special grounds; and
- It is irrelevant that there is a passing off claim that may continue regardless of a stay.

Practical impact

Whilst some aspects of the Court of Appeal's reasoning can be criticised, the effect on practice in the UK was immediate. The court held that a reactive invalidity finding (i.e. in response to a cease and desist letter) does not constitute special grounds. To avoid the Alicante Torpedo, practitioners immediately started to file first and write later.

This was no doubt an unintended outcome of the court's reasoning. To avoid a 10 year stay, EU-wide rights owners are now filing a claim form (a reasonably simple and inexpensive exercise) in order to obtain a filing date, and then notifying the alleged infringer. If the matter can be resolved, the claim form is never served, and lapses. If the alleged infringement continues, the claim form can be served.

Pharmaceuticals

There has not yet been a reported English case discussing the stay provisions in the context of pharmaceutical trade marks or designs. However the principles gleaned from the existing case law give some guidance as to how such a case may be treated. Urgency was the central tenet of the Court of Appeal's decision in BSkyB: the damage caused by delay was the key factor in proving special grounds. However there are two characteristics of the pharmaceutical industry which could contribute to the urgency of a claim and mean that "special grounds" may apply.

The first is the fixed-term nature of patents. For example, there may be a claim that a brand name or logo for a patented pharmaceutical product infringes another company's CTM or RCD. The alleged infringer will have invested heavily in the marketing and launch of that product so is unwilling to abandon the name, but substantial delay (up to 10 years at OHIM) will result in erosion of the valuable monopoly afforded by the underlying patent. In such a case an infringement claim may be deemed sufficiently urgent to constitute special grounds.

The second relates to the nature of pharmaceutical products. In a similar scenario to the above, there may be no patent issues, but a CTM or RCD dispute could lead to drugs or treatments being kept off the market. The public interest in the availability of medicinal products could mean that a resolution was sufficiently urgent to constitute special grounds. Such public interest arguments were considered by the UK's (then) Patents County Court in Regent University v Regent's University London in relation to adverse effects on prospective university students. The court acknowledged that these arguments had the potential to constitute special grounds, but on the facts found that they did not.

Comment

Whilst owners of CTMs and RCDs in the pharmaceutical sector may have arguments to constitute the special grounds needed to avoid the Alicante Torpedo, it may be prudent to file first (perhaps using the lower cost Intellectual Property Enterprise Court). Of course, these issues don't arise if only national rights are relied upon. It should also be noted that other EU member states have not applied such a strict interpretation to "special grounds" and/or have been more ready to grant interim relief against infringement than the English courts have been.

PROFILE: Rosário Cruz

Rosário Cruz is currently managing director at Furtado-Marcas e Patentes, SA. She has been practising in the IP field for more than 30 years, being appointed as a Portuguese Official Industrial Property Agent and a European Patent and Trademark Attorney. She has attended courses in Marketing, Negotiation, Entrepreneurism and Innovation Management and has spoken at international conferences. She is a member of several IP associations, including a former member of the Board of Directors of ACPI (Portuguese Association of Industrial Property Consultants), a past secretary of the Harmonization Committee of ECTA, a long standing member of PTMG and a contributor for the publication of case law on industrial property for INTA (International Trademark Association). Last but not least, she has a daughter and a son and two adorable grandsons.

Where were you brought up and educated?

In Lisbon, Portugal

How did you become involved in trade marks?

Well, I believe that trade marks are part of my father's genetic heritage … The fact that my father founded his own IP office resulted in the fact that since I was a child, I have always heard speaking about trade marks and patents.

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

Most probably a nurse or a social care assistant.

Which three words would you use to describe yourself?

Cheerful, sincere, committed

Complete the following sentence. "I wish …."

. . . that the world would live in harmony

What was your worst experience in the world of work?

Not to have everything done and organized before going on holidays or to meetings.

What was your biggest work or career mistake and what did you learn from it?

Lack of organization. What I have learnt is that, at the very least, it was really a huge waste of time and not a very intelligent attitude…

What do you do at weekends?

Meet with friends, go out for a (good!) meal, go out of town, organize things at home.

Complete the sentence: If I have time to myself …

…I would read more and I would take a course in History and cooking

What's the best thing about your job?

Contact with people and making friends; the opportunity of knowing people all around the world and travelling. It is also a very interesting, diversified and current activity.

What did you want to be as a child?

A nurse or a social care assistant

What is your biggest regret?

I do not have a specific biggest regret, in the sense that in order to have done things differently I should have known what I know today, which would not be possible.

What is a common misperception of you?

That I am a very easy going person.

What is the best age to be?

In my perspective there is no "best age to be" and it is all about the way you feel about yourself, others and everything around you. This being said, I feel that I am now living my best age and I hope to keep in this track !

What is your philosophy in a nutshell?

To always try to count my blessings.

What is your weakness?

A good meal (with dessert!) and good wine …

Whom do you most admire and why?

Those people that try to understand and respect different opinions and attitudes; those that keep calm and do not lose track in a discussion; those that are intrinsically committed to try to live in harmony and to help others to do the same. In my view, it reveals a great wisdom on the part of such people and it should be extremely liberating.

What is your all-time favourite film?

Phantom of the Opera (musical, Lloyd Weber's version)

What is your favourite holiday destination?

Places filled with history or ancient cultures (Syria, Egypt, Peru…)

What is your favourite drink?

Good red or white wine; Caipiroska.

If you could save only three things from your burning home, what would they be?

My dog, my cat and my parrot!

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