

Law Lore & Practice

PTMG



Pharmaceutical
Trade Marks Group

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Editorial: Who'd be a bird ?

As households the world over prepare for the end of year celebrations, the eternal question "what bird shall we have this year?" comes round again. Turkey, goose, duck, pheasant and all of our feathered friends quake at this time of year in Christian cultures. Across the pond, every year Thanksgiving launches the beginning of the end for the turkey and in 2015 it is estimated that 46 million turkeys with an average weight

of 16 pounds each were eaten over the most important US national holiday weekend. Thanks to a recent school quiz, I learnt that President George Washington issued the first national Thanksgiving Day Proclamation in the year 1789 (while the French Queen was summoning the people to "eat brioche") and again in 1795. Abraham Lincoln set aside the third Thursday in November as the official Thanksgiving day in 1863 but it was restored to its original position of the final Thursday in November by President Franklin D. Roosevelt in 1939 to make the Christmas shopping season longer and thus stimulate the economy.

It would be foolhardy to disassociate the end of year festivities from their economic impact, as recent global initiatives such as Black Friday have shown. Undeniably, poultry farmers desperately need the last three shopping weeks before Christmas to reach their projected targets. It is therefore most unfortunate that the current outbreak of avian influenza is spreading so rapidly. According to the British government website, poultry keepers

across the country must now keep farmed birds away from wild birds, including housing them indoors. The World Health Organisation website is even more alarming as it indicates that the National Health and Family Planning Commission (NHFPC) of China has notified the WHO of two laboratory confirmed cases of human infection with the A(H5N6) influenza virus.

At this point, one does wonder whether going vegetarian or even vegan for Christmas might not be an option... A delicious dish of roast vegetables and nut based stuffing could surely suffice. However, it is interesting to note that turkey is listed among the top 10 foods for your eyes because it is rich in zinc, which, along with the B-vitamin niacin contained therein, helps to protect against cataracts. The answer seems to be therefore, know your bird! Local farmers' markets have been increasing their presence year on year and recently many of my neighbours have indulged in the latest fashion of sharing allotments and keeping their own chickens. Short food supply chains are leading the way to enhancing public health and are bringing into question many accepted principles from the recent past. As an example, PTMG delegates were lucky enough to taste the delicious, antibiotic-free Norwegian salmon during our Autumn conference in Oslo.

Whatever your choice of meal, whichever day you choose to celebrate, on behalf of the PTMG committee I take this opportunity to wish you all a happy and healthy festive season and look forward to seeing many of you at our conferences in 2017.

Vanessa

US Update

Jonathan S. Jennings, Pattishall, McAuliffe

On 14 January 2017, the Trademark Trial and Appeal Board (TTAB) of the United States Patent and Trademark Office (USPTO) will implement its most significant changes to its Rules of Practice in almost 10 years. The TTAB reasoned it was due for a set of rule changes in order to adapt to the changing technological times, the updated Federal Rules of Civil Procedure, and the recent precedential decisions of the TTAB and the courts. These changes affect the method of filing documents with the TTAB and the associated filing costs, service of complaints, and discovery. A few of the notable changes are discussed below.

The amended rules change several aspects of the discovery process in the TTAB. The requests for the production of documents and requests for admission will be limited to 75 each, although parties can move to request more for good cause. Most companies will probably view this new limitation as a positive development. Also, discovery must now be served early enough in the discovery period to ensure

that all responses and discovery will be completed by the close of discovery. In the past, some requests could be served on the last day of discovery.

All filings with the TTAB must be made electronically. The only exception to this new rule is for Examining Attorney filings in ex parte appeals. In addition to the paperless filing changes, the filing fees are also changing. The per-class fee for an initial trade mark application using the regular Trademark Electronic Application System (TEAS) is increasing to USD \$400 (up from USD \$325). On the other hand, the per-class fee for a request for an extension of time to file an electronic statement of use is decreasing to USD \$125 (down from USD \$150). Note that the Amended Rules also changed many other fees, including the fee for filing a petition to cancel (USD \$400 up from USD \$300) and the fee for filing a notice of opposition (USD \$400 up from USD \$300). For a list of all fee changes under the Amended Rules, visit <https://www.uspto.gov/trademark/fees->

[payment-information/trademark-fee-changes](#).

In 2007, the USPTO's amendments to the rules changed the service requirement by requiring the plaintiff, rather than the TTAB, to serve the complaint on the defendant. In a surprising change, the new rules reflect a reversal in course by shifting the service responsibility back on to the TTAB, which will serve everything electronically.

The changed Rules of Practice should be reviewed if you have a case before the TTAB. There are several other significant changes to the Rules, and the changes apply to all future and pending proceedings before the TTAB as of 14 January 2017. For more information about all the changes, please review: Miscellaneous Changes to Trademark Trial and Appeal Board Rules of Practice, 81 Fed. Reg. 69950 (7 October 2016) (Final Rules Notice), available at <https://www.gpo.gov/fdsys/pkg/FR-2016-05-27/pdf/2016-12571.pdf>.



The year 2016 is nearing its end which is a good opportunity to look back and reflect on our achievements, but also to look forward and see what is to come next year.

Again we have seen two successful PTMG Conferences this year: After our Spring Conference at the Savoy hotel in London we went to Oslo for the first time. Both our conferences were again fully booked. We were really blessed with an impressive number of highly knowledgeable, dedicated and talented speakers who did a great job. At the PTMG Committee we received plenty of very positive feedback especially on the content of the conferences. Thank you for that! This is very encouraging and seems to mean that we are on the right track when identifying presentation topics and choosing speakers. We promise that we will do our best to keep this high level of participants' satisfaction.

Also our new website was launched in Autumn shortly before the start of the Oslo conference which with no doubt is a real improvement. I had already announced earlier that we have lost three PTMG Committee members Rosina Baxter, Isabelle Dini and Marcus Goldbach. They have left quite a gap and we are very sorry about this. However, I am happy to announce that the PTMG Committee was able to take two new members on board: Tapio Blanc of Roche and Jonas Koelle of Merck KGaA. Both gentlemen have a vast experience in the world of pharmaceutical trademarks and I am very pleased that they have accepted our invitation to join the PTMG Committee.

I am already looking forward to the year 2017 which will first take us to Paris in Spring which seems to be the place to be at that time of the year. The programme for Paris is almost finalized and will hopefully find your approval. It will be published in mid January when registration starts. As always members will receive an email invitation when registration opens. And later next year we will go overseas again, this time to Toronto. Wow!

I wish all the PTMG members, your families and friends a Merry Christmas and a Happy New Year.

Frank Meixner

Members News

New Members

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

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Moves and Mergers

Darren Saunders has left Manatt Phelps & Phillips to join Wilson Keadjian Browndorf LLP in New York, USA. Darren can now be contacted at
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Sema Salman Sinmez has left NSN Law Firm to join the telecommunications company, Turkcell İletişim Hizmetleri AS, in Istanbul, Turkey. Sema can be contacted at
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Please remember to let us know of any changes to your contact details. You can notify me either via the PTMG website www.ptmg.org or directly to Lesley@ptmg.org or by writing to me at Tillingbourne House, 115 Gregories Road, Beaconsfield, Bucks, HP9 1HZ

Lesley Edwards
PTMG Secretary

Germany: Summary of product characteristics under direct attack

Dr. Ralf Möller, Esche Schümann Commichau, Hamburg, Germany

Back in 2013, the German Federal High Court of Justice fundamentally summarized the conditions established by the German jurisprudence for the lawfulness of pharmaceutical advertising and ruled on the significance of the marketing authorization and the product characteristics. In its landmark decision “Basisinsulin mit Gewichtsvorteil”, the court deemed certain claims which were made without referencing any study to be covered by the marketing authorization and/or the summary of product characteristics and therefore decided that these statements were not misleading.

Thanks to the clear words of the German Federal High Court of Justice regarding the evidentiary value of the marketing authorization and/or the summary of product characteristics, it became advisable to even more thoroughly review to what extent healthcare-related advertising information can, as a matter of law, be evidenced in specific contexts with the marketing authorization and/or the product characteristics alone. By doing so, both the imponderables in connection with legal interpretations of scientific studies (a common issue in legal proceedings) and a possible prohibition of the advertising on account of its being misleading, could be avoided.

In a recent decision dated 7 May 2015 “Äquipotenzangabe in Fachinformation”, the German Federal High Court of Justice updated this jurisprudence and specified it in greater detail.

In the case to be decided, the plaintiff took direct action against the – in its view – misleading content of the summary of product characteristics itself and not merely against the statements made in the advertising referencing said summary. The subject of scrutiny was a statement that a certain dose of a certain pharmaceutical would have the same effect as another medicine. The plaintiff asserted that this equipotency statement was not supported by sufficient scientific evidence.

The court of appeal dismissed the complaint. According to the court, the content of the summary of product characteristics was beyond legal review due to the legitimizing effect of the marketing authorisation granted by the German Federal Institute for Drugs and Medical Devices (BfArM).

The German Federal High Court of Justice dismissed this view by referring to the principles summarized in the “Basisinsulin mit Gewichtsvorteil” decision. According to the court, even statements in the summary of product characteristics are capable of being misleading if they are supported by studies that do not justify such claims.

The statements contained in the summary of product characteristics are seen as commercial actions of the pharmaceutical company within the meaning of § 2 para. 1

no. 1 of the German Act Against Unfair Competition (UWG) aimed to promote the sales of its pharmaceutical products. According to the court, the summary of product characteristics is an additional source of information extending beyond the content of the package leaflet which is made available to doctors for their consideration in choosing therapies. Thus, public health will be jeopardized in both cases just the same so that it makes no difference whether a misleading health-care-related advertisement is directly targeted to consumers or professional groups or whether a doctor’s therapy decision is influenced on account of some misleading statements in the summary of product characteristics lacking scientific evidence.

The court went on to say that it is a legal option for the plaintiff to shake the confidence in marketing authorization’s indicative assumption that there is sufficient scientific evidence of the statements contained in the summary of product characteristics in accordance with the principles established in the “Basisinsulin mit Gewichtsvorteil” decision.

In this specific case, however, the plaintiff was unable to furnish evidence to this effect so that his action was dismissed.

Comment

Thanks to this most recent decision, for the first time, the summary of product characteristics of a pharmaceutical comes into the unfair competition law focus and is forfeiting its privileged position. So far, pharmaceutical companies have had no opportunity to participate in the marketing authorization procedure of a competitor or to contest an erroneous assessment of the authorization authority regarding the safety, effectiveness or quality of a pharmaceutical product.

The “Äquipotenzangabe in Fachinformation” decision now opens the door for competitors to directly attack certain statements of the summary of product characteristics providing them with new and far-reaching legal remedy options. It now becomes possible not only to prohibit certain advertisements but also the distribution of the summary of product characteristics itself.

For this reason, it is advisable for pharmaceutical companies to regularly review and update the summary of product characteristics as to whether or not the content and information of said product characteristics are still in line with the current state of scientific knowledge. Otherwise, there is the risk that competitors will attack the summary of product characteristics as misleading by invoking new scientific evidence which became known after the marketing authorization date or which were not accessible to the authorization authority when it made its decision.

EUROPEAN UNION

Chris McLeod and Viktoria Vakratsa, Elkington + Fife

The General Court has ruled in favour of Boehringer Ingelheim Pharma GmbH & Co. KG (Boehringer) following an appeal by Laboratoire de la mer (Laboratoire).

Boehringer owns an EU trade mark registration of RESPIMAT covering pharmaceutical preparations and instruments and apparatus for inhaling pharmaceutical preparations in classes 5 and 10. Boehringer opposed Laboratoire's EU trade mark application for the mark RESPIMER covering pharmaceutical preparations and medical apparatus and instruments for treatment of symptoms in the respiratory system in classes 5 and 10, and other goods in class 3.

Decision

The General Court has upheld the decision of the Fifth Board of Appeal (the Board) of January 2016 and rejected the EU application on the grounds of likelihood of confusion under article 8(1)(b) of EU Trade Mark Regulation No. 207/2009.

Laboratoire argued that the Board's decision was lacking legal basis, because it failed to explain why it did not rely on a prior French trade mark office decision, rejecting an analogous opposition by Boehringer to the RESPIMER mark. The General Court confirmed the decision of the Board in that national decisions are taken into consideration without being given decisive weight, and that the EUIPO is not bound by national court jurisprudence.

In response to Laboratoire's second plea, the Court could not find sufficient supporting evidence to overturn the Board's decision and thus upheld that general references to documents cannot compensate for failure to set out the essential supporting evidence. The Court rejected Laboratoire's claim of alleged similarities between the goods in question.

Another point raised by Laboratoire was that the Board had failed to take into account the conceptual differences between the two marks. In essence, the Court held that despite the common component 'RESPI', the suffixes 'MER' and 'MAT' were considerably different, as the former refers to the French term for sea while the latter may be considered to mean 'material' or 'automat'. This difference, according to Laboratoire, was sufficient to demonstrate a lack of likelihood of confusion. However, the Court upheld the refusal of the mark due to the visual and aural similarities and confirmed that marks should be assessed in their entirety.

Laboratoire concluded its pleas by arguing that the Board's assessment of the

comparison of marks was misconstrued, as the earlier mark was used in relation to a combination of products. In fact, the genuine use assessment of the earlier trade mark showed that the mark had been used in relation to a combined product, consisting of an inhaler under the trade mark Respimat, in conjunction with the pharmaceutical preparation Spiriva Respimat. However, the Court confirmed again the Board's position that the comparison must be made between marks as registered and applied for, whether or not they are used in combination with other marks or indications.

Comment

Laboratoire's arguments did not persuade the General Court to overturn the Board's decision. Arguably, the relevant public, with a higher level of attention due to the nature of the goods, might be confused due to the overall similarities between the marks. It is also worth highlighting the different approach of the EUIPO from that of the French trade mark office, as it confirms a lack of harmonisation between the EUIPO and national trade mark offices.

INDIA

Samta Mehra, Remfry & Sagar

Deceptively similar trade marks have by and large met restraint, more so when these pertain to the pharmaceutical domain. A recent case of GlaxoSmithKline Pharmaceuticals Ltd. & Anr. v Sarath Kumar Reddy reiterates the principal of 'exacting judicial scrutiny' in case of pharmaceutical products. At the same time, interestingly, this case witnessed the Court's refusal of grant of punitive damages to the Plaintiff, marking this as a significant development.

The Plaintiffs - GlaxoSmithKline Pharmaceuticals Limited and Smithkline Beecham Limited (GSK group), engage in the business of manufacturing and marketing a wide range of pharmaceutical/medicinal preparations and healthcare products, and are proprietors of several registrations for GSK and other related marks in various classes such as 1, 3, 5, 9, 10, 16, 21, 29, 30, 32, 35, 41 and 42. The said registrations are valid and still in force. In 2009, the Plaintiffs learnt of a company named GSK Life Sciences Private Limited through the records of the Registrar of Companies. On enquiries, it was found that the Defendant - Sarath Kumar Reddy, is a Director of the said company and that the company's registered office was a fake address and that no balance sheet or annual returns had been filed by the said company. Thereafter, the plaintiffs filed a complaint under the Companies Act to declare the company as defunct. The said complaint is stated to be pending.

On learning about the use of GSK as part

of the trading style by the Defendant and also as a trade mark similar to the one used by the Plaintiffs, a Cease & Desist notice was addressed to the Defendant which was responded to by stating that GSK in the company GSK Life Sciences Private Limited was an anagram taken after the Director's initials - Dr. Gadikota Sarath Kumar Reddy. This led to a case being filed in this court by the GSK group against this entity. In 2013, this court passed an ex parte ad-interim injunction restraining the defendant from using GSK or any other mark similar to Plaintiff's name/mark/GSK logo. The instant case adjudicates on the suit for permanent injunction moved by the Plaintiff, restraining infringement of trade mark, passing off, damages etc.

Perusing all material offered by the Plaintiffs, the Court agreed on their proprietorship over the GSK and related marks. The defendant's products were also offered to the Court for assessment of similarity re adoption and inscribing of the GSK logo. Holding the infringing products to be deceptively similar, the Court ruled in favor of the plaintiffs restraining the defendants from using GSK as part of their trading style and/or the similar logo by itself or in conjunction therewith.

The Plaintiffs had also prayed for grant of punitive damages. However, the court observed that besides the copies of packaging of infringing products, there was no other material which would indicate the extent of sales by the defendant. Further, the loss to Plaintiff, if any, on account of sales by the Defendant also could not be quantified. Thus, the Court rejected their prayer for grant of punitive damages. This is an interesting development and marks a shift from the recent trend.

KAZAKHSTAN

PETOSEVIC

Kazakhstan's Ministry of Justice has drafted a new law amending and supplementing a number of intellectual property laws and regulations, with an aim to make Kazakhstan's IP legislation fully in line with the Organization for Economic Cooperation and Development's (OECD) standards in the area of IP protection and with the Singapore Treaty on the Law of Trade marks.

The Ministry of Justice has recently held public hearings on the draft law, which aims to introduce the following changes:

- A single-level system for the registration of IP rights, i.e. all registrations to be handled by the National Institute of Intellectual Property (NIIP), as opposed to the current two-level system where both the NIIP and the department for IP-related rights within the Ministry of Justice are involved;

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International Update

- An appeal board to be created within the NIIP to handle potential appeals against NIIP's decisions, instead of going directly to court;
- Stronger enforcement measures, including fair compensation to IP rights owners;
- Simplified recording of license, sublicense and assignment agreements – currently, four originals of the agreement are needed for the recordal, but according to the draft law, only a certified copy or extract of the agreement will be required;
- Harmonization of the 'exclusive license' definition with that of the Singapore Treaty – according to current regulations, a licensor retains his right to use a patent, trade mark, industrial design or plant variety even after transferring his license to a licensee. According to the draft law, this right will truly be exclusive to the license holder, that is, the licensor will lose his IP right once he transfers his license;
- Clarification of what is to be done with original goods found in the same shipment with counterfeit goods – they are to be transferred to the rights holder or to their representative, provided that their appearance or purpose have not been altered; and
- Clarification regarding proof of use of a trade mark – the use of a registered trade mark in a slightly different form that does not influence its distinctiveness should be considered as proper use and cannot be grounds for cancellation.

RUSSIA

PETOSEVIC

In June 2016, the Russian PTO announced the beginning of public discussions on the introduction of the trade mark opposition system in Russia, the main goal of which is to shorten the trade mark registration process from the current 12-18 month period to 6-12 months.

The proposed trade mark opposition procedure stipulates that, once a trade mark application is received, the Russian PTO conducts a formal examination on absolute grounds within 3 months of receiving the application and if no absolute grounds for refusal are found, the application is published so that third parties can file oppositions, within the next 3 months.

If nobody objects to the application, the registration process continues; if an opposition is filed and the parties fail to reach an agreement within 6 months, the examiner considers the opposition and issues the final decision.

The current trade mark legislation already provides for certain elements of the opposition procedure, as anyone may file a written notice against any published application before the issuance of the final decision. However, it does not outline a procedure for the consideration of the filed notice, and the other party may not receive a copy of the issued office action or final decision.

The public discussion on the new procedure is still ongoing. During a recent roundtable, a Russian PTO official stated that the new procedure has recently led to an active discussion among professionals, with 49.6% voting in favor of it, 14.1% in favor of it under certain conditions and 36.3% against it.

SINGAPORE

Gladys Mirandah and Chow Jian Hong, mirandah asia – singapore

In *Allergan, Inc and another v Ferlandz Nutra Pte Ltd*, the plaintiffs Allergan, Inc (the First Plaintiff) and Allergan Singapore Pte Ltd, brought proceedings in the Singapore High Court against the defendant, Ferlandz Nutra Pte Ltd (the Defendant) for trade mark infringement relating to the Defendant's use of the First Plaintiff's mark in the Defendant's promotional brochure.

The First Plaintiff was the registered proprietor of the plain word mark **LATISSE** (the Latisse Mark), in relation to "pharmaceutical preparations used to treat eyelashes". The Latisse Mark was applied to an eyelash growth product (the Latisse Product).

LATISSE



The Defendant brought an eyelash growth-enhancement product (the Lassez Product) into Singapore. The Lassez Product was marketed using the unregistered plain word sign and composite sign depicted above.

The Court found that the Latisse Mark and the Lassez Signs were, in their totality, similar. The competing marks were held to be aurally similar. Evidence of the French pronunciation of Latisse was not relevant – what mattered was how the Singaporean consumer would pronounce Latisse and Lassez – which, it was ruled, would result in aural confusion between the two products.

The competing marks were found to be visually similar. Latisse was an inherently distinctive word that was not descriptive of the relevant goods. This made it more difficult to dispel any similarity by virtue of differences in font and colour in the case

of plain word marks. The eyelash device in the Lassez Device Sign did not dissipate the visual similarity because the word Lassez was the dominant feature of the sign, and the device was descriptive of the Lassez Product.

However, the competing marks were found to be conceptually dissimilar. Both competing marks consisted of invented words with no meaning. The fact that the competing marks were based on the same foreign language was insufficient to constitute conceptual similarity.

The Court found that the competing goods were similar, because they had similar uses – both promoted eyelash growth – and were sold in competition with each other, to similar users (medical patients) in similar trade channels (medical clinics).

Accordingly, the Court found that there was a likelihood of confusion between the two marks. The relevant public was held to include not just medical professionals, but also end-users, because end-users were significantly involved in selecting eyelash growth-enhancing products.

Even though end-users would pay a high degree of attention in the purchasing process given that the products were expensive and related to personal well-being, it was found that there was a likelihood that a significant portion of end-users would nevertheless be confused, given the similarity of marks and goods, and given the existence of consumer surveys as evidence pointing towards that outcome.

Although it was held that the similarity was not likely to be sufficient to confuse medical professionals, the likelihood of confusion from the end-users' perspective alone was sufficient to satisfy the requirement of a likelihood of confusion.

The Court held that the Defendant could not avail itself of the comparative advertising defence from its use of the Latisse Mark, because its brochure was materially misleading. The brochure contained a chart, which gave the impression that the Lassez Product achieved better and faster clinical results than the Latisse Product. However, the chart's fine print showed that it did not in fact reveal which product delivered better results, because the basis of measurement for the graphs was not derived from a head-to-head comparison. Even if medical professionals might be expected to read the fine print in the chart, the same could not be expected of end-users.

In conclusion, the Defendant was found liable for trade mark infringement.

PTMG 93rd Conference – Oslo, Autumn 2016

“A Taste of Trade Marks”

Rachel Conroy, Partner at Boulton Wade Tennant, London

Oslo was the destination for this year’s Autumn conference and whilst poor weather can be expected from the region at this time of year, the sun shone beautifully for the 400 delegates in attendance.

Norway, known for its strong economy and plentiful salmon, made for a fabulous location for the event. PTMG delegates from all over the world arrived at The Radisson Blu Plaza hotel for a welcome reception in the Sonia Henie Ballroom Foyer; the Ballroom being dedicated to the Norwegian Olympic Champion figure skater and film star of the 1920s and 30s.

Chairman Frank Meixner welcomed the delegates in his opening remarks on the Thursday morning, noting the new and improved PTMG website which had launched only a few days earlier and thanking his colleagues for their efforts in its re-design. The speakers’ agenda promised to be as informative and valuable as ever to those involved with pharmaceutical trade marks.



Lars Alnaes

The first presentation given by Lars Alnaes from the Norwegian Pharma Association (LMI) on the topic of “The Norwegian pharmaceutical environment” was a great introduction to Norway and its pharmaceutical industry.

Delegates learned of the importance of pharma in one of Norway’s key markets: sea farming, in which following the introduction of vaccines to salmon, a previously heavy reliance on antibiotics was dramatically reduced and the level of fish production increased. Salmon being a valuable commodity to Norway (and more sustainable than oil) means the importance of this cannot be underestimated.

The next speaker was Thomas Gaarder-Olsen from Onsagers on “What is it like to be in Europe but not in the EU?” – a particularly hot topic for the British delegates! Thomas provided valuable insight into his topic, noting that the title was somewhat misleading since in many ways Norway is more integrated in



Thomas Gaarder-Olsen

the EU than some EU member states. Delegates learned some of Norway’s history, dating back ten thousand years after the ice age when people started living in Norway, up to the current day, when Norway’s GDP per capita is one of the highest in the world. For trade mark practitioners, Thomas reminded delegates that EU trade mark practice and case law is relevant in Norway and, importantly, that Norway is not covered by the EUTM.



Wojciech Krefit

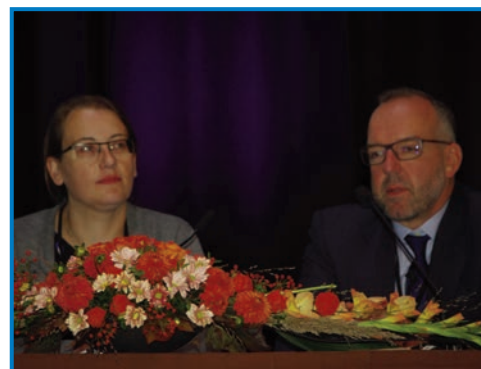
Wojciech took delegates through the key parts of the reform, pointing out that there are many more that the forty minute slot could not accommodate. The Chairman who was involved in the reform, was able to provide an intriguing insight into the compromise involved in the goods in transit provision which was the subject of much political influence and resistance.



Chris Foreman

Next to speak was Chris Foreman of Merck Sharp & Dohme (Europe) Inc. on “Parallel Imports – where are we now?” Chris talked delegates through the established law on parallel imports; a fascinating and complex topic. He guided the audience through the rules in place relating to re-affixing trade marks, re-packaging and re-boxing, and when this is a necessity in practice. Chris was able to provide useful insight into how the packaging of pharmaceuticals has moved with the times: how nowadays more multiples are generally available and how this sits with the necessity condition under the BMS case.

Simon Baggs of Wiggin and Helen Saunders of Incopro took the difficult post-lunch slot and spoke on “ISP Blocking Injunctions – Scalable Enforcement Remedies”. They offered suggestions and solutions for the huge challenge that is



Helen Saunders and Simon Baggs

posed by fake pharmaceuticals and a practical look at remedies for increasingly technical issues. It is a new and growing area of the law but appears to be one in which courts are willing to take a common sense approach and help with the ongoing battle against fake products on the markets.

The next talk was on the subject of “Unjustified threats in the UK and pre-litigation communications” given by Clare Jackman of Norton Rose Fulbright, which applies to claims which would be brought in UK courts. Clare gave a clear insight into what can be a difficult topic and reminded delegates that unjustified threats is a question of fact which can be implied or contingent on future events. She gave some important practice points and took an interesting look at the different approaches to this topic around the world.



Clare Jackman



Jan Peter Heidenreich

Jan Peter Heidenreich of Harmsen Utescher gave the International case round-up. This is a talk usually only given at the Spring conference but at the request of delegates it was being trialled at this Autumn conference. Jan Peter took delegates through some General Court and Board of Appeal decisions on absolute grounds of refusal, followed by EU case law on relative grounds. He also spoke on some German, UK and Canadian decisions, which provided a useful insight into how registries around the world are tackling pharmaceutical related cases.

Delegates met in the hotel reception that evening to be taken to local restaurant D/S Louise, which was situated in a lovely spot by the water. After drinks outside (where heaters were plentiful, thankfully!) we moved into the restaurant for a splendid evening of incredibly good food, particularly given the numbers being catered for. Guests were treated to some of Norway's finest salmon and an interesting goat's cheese ice cream for dessert, which was surprisingly good!

The next morning Philip Cross of Omega Insights and David Slopek of Hogan Lovells gave the first talks of the day in a double session. A fascinating insight into Philip's 40 years of



Philip Cross



David Slopek

branding experience and some key practical advice from David on how to tackle the cluttered registers for pharmaceutical trade marks. Philip took delegates through the evolution of brand names and their influences over time. Both Philip and David highlighted the rejection rate of pharmaceutical brand names by the FDA and EMA, and David was able to provide some useful tips on strategies to adopt for trying to deal with these.

After a coffee break, delegates were provided with a truly interesting Asian update from Clement Ngai of Baker & McKenzie speaking on hot topics in China, Shwetasree Majumder of Fidus Law Chambers



Clement Ngai

speaking on hot topics in India and Young-Joo Song of Kim & Chang speaking on hot topics in Korea. Each speaker informed delegates of key practice points in his or her country and gave a helpful outline of trade mark law that specifically related to pharmaceuticals. In particular, Clement Ngai spoke about the difficulty of obtaining protection for a well-known trade mark in China, the requirements for drug names to be in Chinese and domain name infringement in China. Shwetasree



Shwetasree Majumder

Majumder spoke about trade mark use requirements in India and how the tests for pharmaceutical trade marks are a lot stricter. She also talked delegates through interim injunctions in India as well as explaining what steps are being taken in India to speed up the examination process of trade mark applications. Young-Joo Song explained the systems for trade mark registration in Korea, including expedited examination, goods and services similarity codes, information briefs and the protection of marks famous abroad. She also gave a useful explanation of the practice on medicine names in Korea, including how a trade mark registration is not required, although the drug names are usually registered as trade marks.



Young-Joo Song



Isabelle De Blic-Hamon

After lunch we heard from Isabelle De Blic-Hamon of Nestlé on the topic of "From Food to Nutrition, Health and Wellness". Isabelle provided delegates with an insider's view of Nestlé's expansion from the food and beverage industries to health and science. She advised delegates of the considerations and challenges that Nestlé faces working in the pharmaceutical field, and some of its strategies for trying to overcome them.

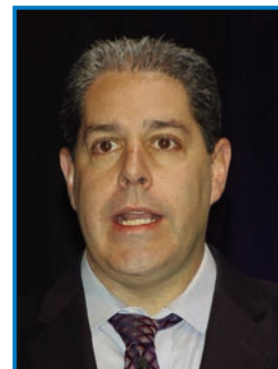
The next speaker was Sven Freiwald of Beiersdorf, the entity behind the Nivea brand, who spoke on the subject of "The borderline between cosmetics and



Sven Freiwald

pharmaceuticals". Sven highlighted the difficulty of distinguishing between cosmetics and pharmaceuticals, particularly in relation to products which have a secondary purpose and can fall across both fields. He informed delegates that the matter must be dealt with on a case by case basis, as is so often the case in trade mark law, but also that if there is any doubt then pharmaceutical legislation applies since this is stricter.

To round off the conference, Marc H. Trachtenberg gave a resounding and dynamic speech on "3D Printing and its Impact on Trade Marks and Copyright". Firstly defining 3D printing more as Additive Manufacturing, Marc used



Marc H. Trachtenberg

video footage to demonstrate to what extent this revolution is now present across every industry from Formula 1 racing, construction and even food. The simultaneous decrease in price and increase in sophistication is bringing the technology ever closer, even right into our homes. Marc provided a detailed analysis of the various risks to IP owners in this moving environment, for example where manufacturing is so local it doesn't cross borders and thus renders enforcement more difficult. He concluded with some practical suggestions as to effective enforcement policies looking towards the future.

The Chairman closed the conference by inviting us to be on time for the coaches to the Gala Dinner held at Gamle Logen, where thankfully the food served was considerably better than the additive marketing pizzas the last presentation had shown us on screen! After thanking all the speakers and sponsors, the Chairman then announced that the 2017 Autumn conference will be held in Toronto. As ever, delegates showed their enthusiasm for this destination and then enjoyed the final moments of the Oslo Autumn conference late on into the night.

94th PTMG Conference

Paris

13th - 14th March 2017

Registration will open mid January

UK Court of Appeal confirms that sale of grey goods may amount to a criminal offense

By Rachel Wilkinson-Duffy and Dr Birgit Clark, Baker & McKenzie, London

In a recent decision (*The Court R v C and others* [2016], 1 November 2016) the Court of Appeal of England and Wales held that a criminal offence under section 92(1)(b) or (c) UK Trade Marks Act 1994 is not limited to counterfeit goods, but can also be committed through the sale, distribution or possession with a view to sale, or distribution of grey goods in the UK., i.e. in cases where the trade mark was applied to the goods with the trade mark owner's consent as opposed to where the goods were counterfeit or fake goods.

This decision will be of interest to owners of pharmaceutical trade marks that often encounter grey goods, since it provides both the stronger deterrent of liability to imprisonment and a fine for those guilty of the offence of trading in such goods and the greater speed of criminal proceedings.

The case

The defendants were accused of unlawfully selling various trade marked products in the UK, whereby some of the goods were counterfeit and others were grey goods, i.e. the goods concerned had been manufactured in factories authorised by the trade mark owner but had then been put onto the market for the first time without the owner's consent. It is important to note that while all goods concerned had been imported into the UK from outside the European Economic Area (EEA), it was not the allegation of the prosecution that these goods were parallel imports. The prosecution in the case maintained that the goods had not been put into circulation with the consent of the proprietor anywhere in the world.

In its decision of 1 November 2016, the Court of Appeal confirmed that all aforementioned types of goods fall under the ambit of the criminal provision in section 92 UK Trade Marks Act 1994 Act (section 92). The court based this on the following considerations: the wording of section 92 UK Trade Marks Act 1994 (a sign identical to, or likely to be mistaken

for a registered trade mark) is clearly meant to comprise circumstances where a sign identical to the registered mark had been applied, regardless of the proprietor's consent. The judges rejected the defendant's rather creative argument that there is a distinction between an identical sign - which it was argued could only be applied by someone other than the proprietor, as otherwise it would be the application of the registered mark, not a sign identical to the registered mark - and the registered mark itself; thus the scope of section 92 UK Trade Marks Act 1994 should be treated as restricted to goods for which the proprietor did not authorise the application of the registered mark. The Court of Appeal also referred to the leading textbook in the field, Kerly's, parliamentary debate and a recent precedent in *Genis* [2015] EWCA Crim 2043 where a criminal conviction was upheld even where a trade mark had originally been applied with the owner's consent. Finally, the judges stressed the importance of public policy considerations, the potential negative effect on brand value and the "very real issue of public health and safety [that may] arise where the goods are rejected as substandard but nevertheless sold without authorisation".

The court also took the opportunity to clarify the concept of grey goods: these could include, inter alia, goods made as part of an order placed by the trade mark owner with an authorised manufacturer but which had then been cancelled, subsequently rejected due to not being of sufficient standard or in excess of the ordered amount.

In this context, it is important to note that in cases of a criminal offence and that anyone able to show a belief on reasonable grounds that the use was not an infringement, will not be caught by section 92 UK Trade Marks Act 1994. The judges also stressed that the facts of the case did not require a determination of whether parallel imports of genuine goods from outside the EEA region put on the market by and/or with the consent of the trade mark owner fall

within the scope of section 92 UK Trade Marks Act 1994. However, the implication from reference in the decision to Kerly's definition of grey goods to include parallel imports does suggest a leaning in favour of this.

Practical significance

This decision will be of specific interest to owners of pharmaceutical trade marks since it provides helpful confirmation that the trade mark offences under section 92 UK Trade Marks Act 1994 not only apply to counterfeit goods but also to the distribution and sale of grey goods bearing the trade mark. This will allow trade mark owners to pursue private criminal prosecution in addition or as an alternative to involving Trading Standards. While parallel trading can be inter-linked with criminal activity, including counterfeiting but also serious organised crime, the limited resources available to Trading Standards in the UK require a focus on criminal prosecution where there is a clear concern for consumer safety and/or suspected organised crime. It is therefore unlikely that Trading Standards would be able to justify devoting resources to pursuing criminal sanctions for "genuine" pharmaceutical products (which have been manufactured with consent, comply with regulatory requirements and are otherwise fit for purpose), on the sole basis that the trade mark owner's rights have not been exhausted.

Having said that, judicial confirmation that private criminal prosecution is available in such cases provides an additional weapon in the arsenal of pharmaceutical trade mark owners for whom civil liability may not always be a sufficiently adequate deterrent.

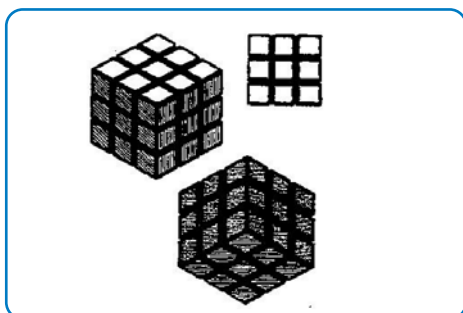
This decision could also potentially lead the way to establishing that parallel imports may amount to a criminal act where the goods have been put on the market outside the EEA with the proprietor's consent and could have even more far-reaching implications should UK exhaustion be adopted post Brexit.

Rubik's Cube: Invisible mechanisms scupper trade mark protection

Clare Jackman and Eleanor Denny, Norton Rose Fulbright LLP

On 10 November 2016 The First Chamber of the ECJ (the Court) gave the final judgment in the Rubik's Cube trade mark saga. The Appellant (Simba Toys) appealed to set aside the judgment of the General Court in which the action to cancel the Defendant's (Seven Towns) Community Trade Mark (No 162784) was dismissed.

The Defendant had registered a 3D sign in class 28, described as a three dimensional puzzle (the Sign).



Simba argued on six grounds why the mark should be cancelled. However, the court only dealt with the ground of appeal based on the General Court's alleged misapplication of Art 7(1)(e)(ii), which states that signs that consist exclusively of the shape of goods which is necessary to obtain a technical result shall not be registered. Simba argued, under this ground, that the General Court was wrong in determining that the provision only "bites" where technical results may at least be "inferred with sufficient certainty" from the graphical representation of the mark concerned. According to Simba, no such requirement could be inferred from the wording of the provision or from case-law. The Court agreed and stated that the correct application of Art 7(1)(e)(ii) requires that the essential characteristics of the three-dimensional sign at issue be properly identified and assessed in light of the technical function of the actual goods concerned. This implies a need for examiners to undertake a degree of investigation and not just take graphical representations at face value.

Below are set out two key points that the Court discussed in this case relating to the application of Art 7(1)(e)(ii).

(1) Do the essential features perform a technical function?

The conclusion of the General Court was that the essential features of the Sign were the cube shape and grid structure on the

surface. The General Court decided these features could not constitute or signal a technical function based on their conclusions drawn from case law.

However, the Court disagreed and instead agreed with the Attorney General that as the Sign consisted of the shape of the actual goods (not an abstract shape) and, following Lego, it was essential the shape must be assessed in light of the technical function of those actual goods. This technical function should be taken into account when assessing functionality of essential features.

Furthermore, following Yoshida, the Court stated that when assessing signs a competent authority may carry out "detailed examination" of materials relevant to identifying essential features in addition to the graphical representation of the sign and description. The Court highlighted that following the Philips, Lego and Yoshida cases a competent authority would not be able to analyse the shape purely on the basis of the graphical representation but would instead need to also consider additional information on the actual goods; for example, knowledge of the goods' purpose and/or use and any other IP filings e.g. patent filings in the Yoshida case.

(2) Public policy reasoning behind Art 7(1)(e)(ii)

The Court stated that the objective of Art 7(1)(e)(ii) is to prevent an undertaking from being granted a monopoly on technical solutions or functional characteristics of a product. The Court was concerned by the fact the sign in this case was registered for three dimensional puzzles and nothing in the description limited this to puzzles with rotational capabilities.

The Court stated that simply not mentioning rotational capabilities could not preclude them from being taken into account when examining functionality. Furthermore, the Court stated this broad description would allow Seven Towns to monopolise both rotational and non-rotational 3D puzzles and the Court felt it was contrary to public policy granting such a broad monopoly.

Therefore the Court agreed with Simba that the Community Trade Mark should be cancelled as it breached Art 7(1)(e)(ii).

Points to take away:

(i) This case and those mentioned in the judgments detailed above dealt with signs

that comprise the shape of the actual goods they relate to, rather than mere abstract shapes. However, the courts have not clearly defined what would be counted as the actual shape or an abstract shape; for example, in Yoshida a 2D simplistic handle shape was deemed to be a sign in the actual shape of the goods (a knife), albeit only part of those goods. Therefore, while there may be uncertainty as to whether these judgments will apply to a mark if it is not clear if its shape is that of the goods, it appears the courts' interpretation of what would be deemed to be the shape of actual goods will be broad.

(ii) The courts stated "additional information" should be considered beyond the graphical representation and description of a trade mark when assessing function of essential features. However, it is unclear what such "additional information" would include. In Yoshida the court used merely permissive language saying competent authorities "may" carry out detailed examinations. This was followed by the Court in the current case. Furthermore, the courts have not set out clearly to what level of detail the competent authorities must research products before they approve registration.

(iii) It has been noted that recently the courts have been reluctant to grant trade mark protection for shape marks, applying more stringent criteria and relying on the point that trade marks should not be used to grant an unlimited monopoly on technical functions for public policy reasons (for example the Kit Kat case and Taxi Cab case). Parties must make sure trade marks are only used to protect their brand and should consider using other IP rights, e.g. patents and design rights, if they are more appropriate.

ERRATUM

In the PENTASA v XENASA article on page 8 of the September edition of LL&P, the mark referred to as XANTASA should of course have read XENASA.

Parallel import and repackaging of pharmaceutical products in Turkey

Gökçe Izgi and Merv Atinay, LL.M. Moroglu Arseven

While the European Union has long determined its approach to trademark issues for parallel imports and repackaging of pharmaceuticals, Turkish courts and legislation lack a unified and established practice on the issue. In fact, the current regulatory regime in Turkey prevents parallel import and repackaging of pharmaceuticals.

Key aspects of trade mark law for pharmaceuticals

Pharmaceutical imports into Turkey are regulated under the Pharmaceutical and Medical Preparations Law numbered 1262 (Law numbered 1262), while parallel imports and the exhaustion of rights principle are regulated by the Decree Law on the Protection of Trade marks numbered 556 (Trade mark Decree Law). These legislative instruments aim to protect public health and intellectual property respectively. However, in practice the differing motivations also lead to contradictory outcomes in interpretation.

One of a company's most important assets is its trade mark portfolio. The key functions from a commercial trade mark portfolio are to:

- Exclusively identify and guarantee the commercial source or origin of products or services;
- Distinguish the trade mark owner from other establishments;
- Enable consumers to be certain that a purchased trade marked product has not been subject to interference by a third party, without the proprietor's authorization; and
- He or she will enjoy the same quality every time they purchase products from the same brand.

Legal systems generally allow trade mark holders to enjoy these functions by granting the right to prevent third parties from using its trade mark on goods or packaging, as well as prevent the goods being imported or exported. However, limitations apply to this absolute right, including the exhaustion of right principle.

Article 13 of the Trade mark Decree Law explicitly includes the national exhaustion principle as follows. The acts related with a product containing a registered trade mark shall not constitute a breach of the rights of a registered trade mark, where such acts have occurred after the product has been put on the market in Turkey by the proprietor or with his consent. The proprietor has the right, even within the provision of the first paragraph, to oppose further commercialization of the goods, especially where the condition of the goods is changed or impaired after they have been put on the market.

For a right to be exhausted under Article 13, goods must be sold in Turkey either by the trade mark owner, or by third parties with the owner's consent. It is agreed that

what becomes exhausted is the right to first sell trade marked goods and not trade mark rights. Therefore, considering the fact that Turkey accepts the national exhaustion principle, the Trade mark Decree Law actually allows trade mark owners to prevent parallel import. If a third party imports goods to Turkey other than the goods in question, which have been already sold in Turkey, the trade mark right is not exhausted for the later goods. Therefore, the trade mark holder can prevent sale of those goods in Turkey.

However, the Court of Appeal interprets the exhaustion of rights in broader terms. In numerous decisions, it has concluded that if goods bearing the registered trade mark are put on the market in Turkey, the exhaustion of rights occurs for all similar goods put on the market in other countries. Therefore, it is not possible to prevent importation or sale of original goods in Turkey, which have been put into the market of the other countries, unless the products are altered or damaged.

Parallel Importing of Pharmaceuticals

Parallel importing involves products being legally made (i.e. not pirated) abroad, but then imported without the intellectual property right-holder's permission. The concept has always been debatable due to the potential advantages which parallel importers gain, as well as possible loss of benefits for trade mark holders and the necessary changes which must be made to original packaging. These issues are particularly relevant for parallel imported pharmaceuticals.

Due to pharmaceutical pricing policies (based on consumer purchasing abilities) and the structures of state health and insurance practices, the same product is often marketed for different prices by different companies. Parallel importers buy original pharmaceuticals from one market at a lower price, then sell them in other markets for a higher price.

Trade mark holders argue that parallel imports harm trade marks' guarantee function. That is, the trade mark holder cannot guarantee the product's quality, since it cannot guarantee that products are kept under the right conditions during parallel importing, nor whether the packaging (including expiry date) has been manipulated.

On the other hand, parallel imports are arguably a strong tool for competition law, enabling international trade to function by preventing the trade mark holder from partitioning markets and allowing goods to move freely.

Parallel Importing in Turkey

Given Turkey's ongoing European Union harmonization process, the CJEU's decisions could potentially serve as

valuable guides for Turkish courts and judges in developing a local approach. However, the current regulatory regime in Turkey prevents parallel import and repackaging of pharmaceuticals.

The Turkish Court of Appeal interprets parallel imports widely, failing to take into account the difference between goods which have already been put into the market and later imported goods. However, despite the more liberal judicial approach, pharmaceuticals are strictly regulated in Turkey, with close regulatory control over standards and pricing for manufacture, distribution, sale, promotion, imports and exports.

Accordingly, pharmaceuticals can only be imported and commercialized by the company which holds marketing authorization from the Ministry of Health. Marketing authorization is granted only to the Turkish subsidiary of the pharmaceutical manufacturer. Therefore, since it is only granted to one company, practically other companies are not allowed to import the pharmaceutical. These restrictions mean that parallel import of pharmaceuticals is not allowed in Turkey.

Labelling is also closely regulated by Law numbered 1262 and the Regulation on Packaging and Labeling of Pharmaceuticals (Regulation). The Regulation explicitly and strictly determines packaging requirements, also requiring packaging changes to be reviewed and approved by the Ministry of Health. Therefore, repackaging of pharmaceuticals is prohibited in Turkey.

When applying for marketing authorization, applicants must prepare sample packaging and submit this to the Ministry of Health for approval, together with other application documents. All information on the packaging and patient leaflets must be in Turkish, including:

- Name of the marketing authorization holder;
- Name of the laboratory where the pharmaceutical was manufactured;
- Marketing authorization number;
- Instructions for using the pharmaceuticals;
- Harmful or poisonous ingredients;
- Whether the pharmaceutical must be sold via a prescription.

Therefore, unless the current regulatory requirements are amended to allow parallel imported pharmaceuticals, the Turkish market will continue to be excluded from the economic benefits provided by parallel imports. For example, preventing division of markets and lowering the risks of companies abusing dominant positions.

Therefore, it seems that for now, Turkey will continue to watch European Union parallel import developments from a distance.

PROFILE: Fran Jagla

Fran Jagla focuses her practice on trade mark, copyright, Internet domain name matters and unfair competition counselling. She has extensive U.S. and international experience in name development, clearance filing, registration, maintenance and enforcement of trademarks and copyrights for Fortune 100 companies as well as start-ups and emerging companies. World Trademark Review 1000 listed Fran as a top individual in the trade mark practice, describing her as a “skilled, proactive and resourceful” adviser who is a “powerhouse — especially in the pharmaceutical trade marks domain” and that her “celebrated non-contentious skills are put to good use on trade mark, labelling and domain name assignments for pharmaceutical manufacturer such as Endocyte, Incyte and Upsher-Smith Laboratories.” Fran has worked in-house for Miles Laboratories (now Bayer USA), was lead trade mark counsel at Abbott Laboratories for 15 years, then went on to lead the Trade Mark group at Microsoft. After leaving Microsoft, she took her first foray into the realm of outside counsel and joined Leydig, Voit and Mayer in their Seattle office. She joined Lane Powell PC 4 ½ years ago and continues her practice in primarily regulated industries: pharmaceuticals, medical devices, spirits, wineries and now cannabis. She is a long-standing member of PTMG



Where were you brought up and educated?

Born and raised in South Bend, Indiana, USA. Attended Indiana University with a degree in Political Science, attended Valparaiso University School of Law in Indiana as well. A “Hoosier” education and upbringing. That’s why I have no accent.

How did you become involved in trade marks?

Prior to graduating from law school, there was a posting on our law school job board for Miles Laboratories who were in need of a junior trade mark lawyer and a junior patent lawyer...since Political Science was not considered a real science (per patent rules) I went to trade marks. I didn’t know how lucky I was!

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

General business or corporate law or antitrust.

Which three words would you use to describe yourself?

Calm, Concerned, and, on occasion, Chaotic.

Complete the following sentence.

“I wish”

That there were more hours in the day. And that I had the discipline to learn another language.

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

History, Literature (Don Quixote in the original Spanish was a challenge) and, in Law School, Antitrust.

What do you do at weekends?

Try to organize, wine taste and spend time with my friends and family.

Complete the sentence: I’m no good at. . . .

being mean or unhappy. Life is way too short.

What’s the best thing about your job?

I get to work in diverse industries with clients that I really like and companies I can respect. From pharmaceuticals to spirits and wineries with a bit of everything else thrown in. My days are never the same.

What does all your money get spent on?

Travel, travel and travel.

What is your biggest regret?

I don’t think I have any regrets. Everything that happens in life is a learning experience. What doesn’t kill us makes us stronger! Or smarter!

What would be your ideal night out?

A very dry gin martini (blue cheese olives), a nice dinner at a small bistro and a Broadway musical (preferably a comedy) with my husband. Friends are invited as well.

Who was your mentor or role model?

Mel Silver, Chief Trade mark Counsel, Bayer USA. My first boss who taught me how to be a lawyer and to be the kind of lawyer that I could be proud of. Mel passed away several years ago and I still want to call him to talk through issues at times.

What is your weakness?

That’s an easy one, shoes!

Whom do you most admire and why?

I admire those people that have faced great challenges and adversity and still are

able to maintain a positive outlook.

Which book or books are you currently reading?

I just finished reading Devil in the White City by Erik Larsen for the second time. Great mixture of history and fiction set in the Chicago during the World’s Fair. Along with a serial killer. What could be better?

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

Queen, Bohemian Rhapsody.

What is your all-time favourite film?

South Pacific (the original of course).

Which one person would you invite to dinner (other than a family member or relative)?

Barack Obama. Michelle could come as well.

Which word or sentence do you most often say?

“Let’s step back for a second and think about this” or “Take a breath”. Sometimes I am convinced that people actually try to rile me just to see if they can...

What is your favourite holiday destination?

Wherever my husband, my daughter and her family (including the grandson) are. I like being home for Christmas.

Where do you see yourself in 10 years’ time?

Potentially retired or semi-retired, enjoying the sun, the water and my family.

Which piece of advice would you give a visitor to the area in which you live?

It really doesn’t rain all that much, so don’t complain when it does!