Law Lore & Practice

PTMG Pharmaceutical Trade Marks Group

Sept 2018

How hot can it get?

Here in mainland Europe, we are enjoying an ongoing hot summer, with temperatures reaching 30°C still. This in itself is glorious, an Indian summer always being one of my favourite moments of the year when the feeling of pushing back winter is most agreeable and early al fresco dinners before the light fades are still possible. However, coming on the back of two solid months of wall to wall heat with almost no rainfall, this year also raises questions and concerns which inevitably lead back to global warming. The lawns look like straw, the shrubs are wilting and farmers have long had to resort to feeding their animals with winter feed, posing issues for the months to come.

Two years ago, the World Health Organisation had already warned that 250000 supplementary deaths per annum were to be expected between 2030 and 2050, given the projected impact of climate change on clean air, drinking water and sufficient food supplies. Even on a very local level, some of the insects flying around this year in the gardens have rarely been seen in such quantities – notably May beetles and Asian hornets. Due to increased international travel, illnesses such as the dengue and malaria crop up in conversations more regularly than in the past.

Whilst I am certainly not a Luddite, proning a return to the infamous "good old days", I am entitled to be concerned about my ageing immune system and its ability to adapt to these new environmental conditions and our collective response to them. Ignoring the consequences of mankind's impact on the natural world would be yet another example of the folly of our species. In this connection, Cormak McCarthy's post-Apocalyptic novel The Road should be made compulsory reading – but not just in schools.

I look forward to seeing many of you in Dubrovnik where the balmy evenings (hopefully without mosquitos) will be the perfect occasion to discuss this and pharmaceutical matters – of course!

Vanessa

US Update

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

When a company seeks the review of an ex parte decision issued by the Trademark Trial and Appeal Board (TTAB), one option, other than an appeal to the Federal Circuit, is a direct appeal to a United States District Court. Pursuing this option, however, may result in the unusual circumstance of the company paying the USPTO's attorneys' fees even if the company prevails.

In Shammas v Focarino, 784 F.3d 219 (4th Cir. 2015), the Fourth Circuit affirmed the award of the USPTO's attorneys' fees in a trade mark case finding that such fees constituted 'expenses' under the relevant statute. This summer, by contrast, the Federal Circuit in the patent case Nantkwest, Inc. v Iancu, 898 F. 3d 1177 (Fed. Cir. 2018)(en banc), held that such expenses did not include attorneys' fees.

These contradictory decisions create a 'circuit split' even though Shammas involved trade mark and Nantkwest involved patent law, as the statutory provisions at issue are very similar. The USPTO may seek review of Nantkwest by the Supreme Court. In the meantime, the Fourth Circuit will have the chance to revisit this issue during the pending appeal of the District Court trade mark case Booking.com B.V. v Matal, 2017 WL 4853755 (E.D. Va. October 26, 2017). In that case, the District Court ordered Booking.com to pay USD $51,472.53 in the USPTO's 'personnel' expenses (covering the fees of attorneys and a paralegal). This case has attracted considerable attention as the court ordered Booking.com to pay the USPTO's attorneys' fees even though Booking.com was the prevailing party!

For Pharma companies considering the review of an ex parte TTAB determination, the decision to pursue a direct appeal to a District Court, where it may involve the payment of a significant sum of money for the USPTO's attorneys' fees, may make the option of an appeal to the Federal Circuit more desirable. There is no similar provision for paying the USPTO's attorneys' fees in a Federal Circuit appeal. Nonetheless, a direct appeal to a District Court may make more strategic sense in certain circumstances. The issue of whether a company must pay the USPTO's attorneys' fees could be headed to the US Supreme Court for ultimate resolution. For now, pursuing the appeal of a TTAB ex parte decision to a District Court clearly implicates potentially paying the USPTO's attorneys' fees no matter who wins.

Words from the Chair

Preparing for my summer vacation (again in France, but this time in the Provence) I am still in shock about the latest political developments: President Trump has made a sensational trip to Europe leaving his NATO allies (and especially the Germans) reeling. Afterwards he enjoyed dinner at Blenheim Palace with Theresa May. At the same time the press published an interview where he basically said that May has wrecked Brexit (because she did not sue the EU as he had advised her to do) and that Boris Johnson would make a perfect Prime Minister. Perfect timing, indeed! Well, who needs enemies if you have friends like that? And finally Mr. Trump made an appearance in Helsinki at a summit with Vladimir Putin. Wow, I am still baffled and look forward to my holidays in France where I hopefully will not be exposed to any further world news.

Here in the European IP world Antonio Campinos meanwhile has left Alicante and has taken over his new role as President of the EPO in Munich. At the EUIPO Antonio has definitely left an impressive footprint. We wish him all the best for this new job and at the same time can't wait to see his successor in Alicante appointed.

In early October we will be reunited in beautiful Dubrovnik for our next conference under the title 'Pearls of trade mark wisdom from the Pearl of the Adriatic'. Something to look forward to..... Until then enjoy a fantastic summer (wherever you spend it) and take care!

Frank Meixner

Members News

New Members

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

Evrard van Zuylen of Darts-IP, Clos Lucien Outers 11-21, Brussels, 1160, Belgium evanzuylen@darts-ip.com

Barbara Solomon of Fross Zelnick Lehrman & Zissu, 4 Times Square, 4th Floor, New York, NY, 10036, USA bsolomon@fzlz.com

Moves and Mergers

Marianne Hollands has left Orion Corporation to join Berggren Oy in Helsinki, Finland. Marianne can be contacted at Marianne.hollands@berggren.fi

Sandrine Pernod Boulanger is now with Reflexlegal in Westmount, Quebec, Canada and can be contacted at spernod@reflexlegal.com

Toni Polson Ashton has left Sim & McBurney to join Marks & Clerk Canada in Toronto, Canada. Toni can now be contacted at tashton@marks-clerk.ca

Agnieszka Sztoldman has left Dentons to join SMM Legal in Warsaw, Poland. Agnieszka can be contacted at Agnieszka.sztoldman@smmlegal.pl

Maria Angeles Moreno and **Sergio Gonzalez** have both left Herrero & Asociados to join Arochi & Lindner in Madrid, Spain. Maria can be contacted at amoreno@arochilindner.com and Sergio at segonzalez@arochilindner.com

Tiffany Valeriano has left TrademarkNow to join Corsearch in Aschaffenburg, Germany. Tiffany can now be contacted at tiffany.valeriano@corsearch.com

Steve Anderson from Corsearch has a new email address; steve.anderson@corsearch.com.

Nicole Linker has left Actelion Pharmaceuticals to join Abbott Products Operations AG in Allschwil, Switzerland. Nicole can be contacted at Nicole.linker@abbott.com.

Jennifer Insley-Pruitt has left Fross Zelnick Lehrman & Zissu to join Dechert LLP in New York, USA. Jennifer can now be contacted at Jennifer.insley-pruitt@dechert.com

Coleen Morrison has left Marks & Clerk Canada to join Perry & Currier Inc. in Toronto, Canada. Coleen can be contacted at Morrison@pckip.com

Philip Harris is now Managing Director of Novagraaf UK in London, UK. Philip can be contacted at pharris@novagraaf.com

Wolfgang Danner is now with Billtrader PTY Ltd and can be contacted at wolfgang.danner@billtrader.com

Kana Enomoto has left Maucher Jenkins to join Johnson & Johnson in Allschwil, Switzerland. Kana can be contacted at kenomot1@its.jnj.com

Heidi Gorenstein Nigri has left Luiz Leonardos Intellectual Property to join McLaw – Müller, Cid, Noronha, Cruz & Gorenstein Attorneys at Law in Rio de Janeiro, Brazil. Heidi can be contacted at hnigri@mclaw.legal

Sonia Elkrief formerly with Merck Serono, is now in private practice based in Geneva, Switzerland. Sonia can be contacted at Sonia@elkrief.ch.

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

EU General Court annuls Board of Appeal decision in XENASA v PENTASA

Nina O'Sullivan and Humam Al-Jibouri, Mishcon de Reya LLP

On 19 June 2018, the EU General Court annulled the Fourth Board of Appeal's finding that there was a likelihood of confusion between the marks XENASA and PENTASA. The decision raises interesting issues relating to the impact of the understanding of different types of end-users on the assessment of similarity of signs, and of the likelihood of confusion. The outcome can be contrasted with the General Court's June 2017 decision that there was a likelihood of confusion between OCTASA and PENTASA, in a dispute involving the same parties (see the September 2017 edition of LL&P).

This dispute dates back to 2013, when Tillotts Pharma AG applied to register an EU trade mark for the word sign XENASA in relation to Class 5 goods (pharmaceutical preparations, namely for the diagnosis, prevention and/or treatment of gastrointestinal disorders and conditions; pharmaceutical preparations for the treatment of inflammation of the gastrointestinal tract; dietetic substances adapted for medical use, namely for the diagnosis, prevention and/or treatment of gastrointestinal orders and conditions). Ferring BV filed a notice of opposition based on its earlier EU word mark PENTASA, covering 'pharmaceutical products and substances', also in Class 5. The Board of Appeal annulled the Opposition Division's decision, holding that there was a likelihood of confusion between the marks (see the September 2016 edition). The Board's decision was seen as surprising at the time, given the high level of attention that both the public and professionals display in relation to pharmaceutical products.

In its decision, the General Court agreed that the attention of the relevant public (both professionals and end-user patients) would be high, rejecting the EUIPO's argument that, for dietetic preparations for diagnosing, preventing and treating gastrointestinal disorders, the level of consumer attentiveness should be set at a lower level, namely just above average. The Court also upheld the Board of Appeal's decision that the goods were identical or very similar.

When comparing the signs, the Court paid particular attention to the different categories of end-users. In particular, the Court only partially upheld the Board of Appeal's finding that the descriptive character of the suffix ASA, as a reference to the active ingredient mesalazine, also known as 5-asa, would not be understood by all end-users (the Board's finding had been based on the General Court's first OCTASA decision). Here, the General Court concluded that, given that some end-users may in fact regularly take medications containing 5-asa or mesalazine for treatment of inflammation of the gastrointestinal tract, a significant part of end-users would perceive ASA to refer to that ingredient.

Accordingly, when assessing the visual, phonetic and conceptual similarities between the signs and the likelihood of confusion, the General Court distinguished between

(a) those end-users who would, and those who would not, understand ASA as a reference to the active ingredient 5-asa or mesalazine (which, for example, impacted on how XENASA would be pronounced); and also;

(b) between those end-users who would, and those who would not, perceive the beginnings of the signs as references to the Greek word xenos and the prefix of Greek origin penta respectively (which, in particular, impacted on the conceptual comparison).

For each category of end-user however, the Court concluded that there was no likelihood of confusion.

In contrast, in its June 2017 OCTASA decision, the General Court had decided there was a likelihood of confusion between OCTASA and PENTASA, even though there was only a low degree of aural, visual and conceptual similarity, and despite the higher level of attention that would be displayed by both professionals and end-users. In that case, there was no challenge to the Board's finding that a significant number of end users (as opposed to medical professionals) would not be able to identify the descriptive character of ASA, which had a significant impact on the assessment of similarity of the signs.

The Court's latest decision demonstrates that the assessment of similarity of signs, and of the likelihood of confusion, can be a complex one in relation to pharmaceutical products, particularly where a number of categories of end-users may have varying perceptions of different elements of a mark. In turn, this will impact on the relevant evidence that must be obtained in relation to different categories of user.

PTMG is preparing an anniversary book for its upcoming 100th conference.
Do you have any photographs taken at previous PTMG conferences?

If so, please contact the Editor.

Interlocutory Injunctions and Irreparable Harm

Daniel R. Bereskin, Q.C., Bereskin & Parr LLP

Interlocutory or interim injunctions are attractive to plaintiffs because the grant of an injunction often ends the litigation, at much less cost than a full-blown trial. Pharma cases are no exception. That said, such injunctions are not easy to obtain, and when granted there is a risk of damages to the defendant should the case proceed to trial and the defendant is found not to have infringed.

One important requirement for obtaining such relief is proof of irreparable harm. The issue to which this note is addressed is whether irreparable harm should be presumed if the Court is of the view that the plaintiff is likely to succeed at trial. In the author's view, such a presumption generally is not in the public interest. Instead, Courts should require evidence of likely irreparable harm unless there are exceptional circumstances to the contrary.

For the UK and other commonwealth countries including Canada, the usual starting point is the 1975 judgment of Lord Diplock in American Cyanamid v Ethicon. That case involved absorbable synthetic sutures that were covered by a patent owned by American Cyanamid. Ethicon introduced into the UK market, synthetic sutures intended to compete directly with those of American Cyanamid. Graham, J. granted an interlocutory injunction, which was vacated by the Court of Appeal. On appeal to the House of Lords, the decision of Graham J. was restored.

The reasons given by Lord Diplock were intended to serve as guidelines for the future grant of interlocutory injunctions. They are summarized as follows: (1) there is a serious question to be tried, (2) the plaintiff will suffer irreparable harm if the interlocutory injunction is denied, and (3) the balance of convenience favours the plaintiff. These guidelines in general apply to both trade marks and patents, but there are differences, as indicated below.

The requirement of a 'serious question to be tried' is a low threshold. It is generally considered sufficient if the plaintiff has a possibility of success at trial, rather than a probability of success. It appears that Lord Diplock's guidelines were intended for those cases where it is neither possible nor practical for the Court at an interlocutory stage of the action to make a proper assessment of the plaintiff's chances of success at trial, which is why proof of liability was set low, and proof of irreparable harm and balance of convenience were set high.

In the UK, the relative strength of the respective parties' positions has become a factor, notwithstanding the low threshold test envisaged by Lord Diplock. In Series 5 Software Ltd. v Clarke, Justice Laddie stated that 'Lord Diplock did not intend ... to exclude consideration of the strength of the cases in most applications for interlocutory relief.' This implies a 'sliding scale' approach, i.e. the level of required proof of irreparable harm is an inverse function of the perceived strength of the plaintiff's case. Even so, interim injunctions in trade mark cases remain difficult to obtain in the UK, Canada and other commonwealth countries.

Interestingly, interim injunctions in the UK may more readily be obtained in pharma patent cases than trade mark cases unless the defendant has taken steps to 'clear the way' of any blocking patents prior to entering the market: see SmithKlineBeecham v Apotex and cases that follow. That said, much depends on the relevant facts. In Cephalon v Orchid, an interim injunction was refused essentially based on Cephalon's failure to prove irreparable harm. In Canada, interlocutory injunctive relief in patent cases remains problematic, see Tearlab Corporation v I-Med Pharma Inc., where the Canadian Federal Court of Appeal affirmed a trial judgment refusing an interlocutory injunction in a pharma patent case.

US case law has developed along different lines. Historically, irreparable harm has been presumed once the Court is satisfied the plaintiff is likely to succeed. This has changed as a result of two United States Supreme Court cases: eBay Inc. v MercExchange and Winter v Natural Resources Defense Council, Inc. According to the Winter case, in order to obtain a preliminary injunction, a plaintiff 'must establish that he is likely to succeed on the merits, that he is likely to suffer irreparable harm in the absence of preliminary relief, that the balance of equities tips in his favor, and that an injunction is in the public interest.'

Although eBay and Winter are important cases that indicate the present state of US law, it remains unclear whether it is appropriate for US Courts to apply a 'sliding scale' approach as mentioned above. In the author's view, the fact that an interlocutory injunction is an extraordinary remedy that can affect the public interest as well as the interests of rival traders, means that irreparable harm generally should not be presumed.

There appears to be divergent views among the Federal circuits in the US as to the applicability of a sliding scale test. As a result, in 2017 the Board of Directors of the INTA passed a resolution proposing that the Lanham Act should be amended to provide that 'when a claimant seeks injunctive relief under Section 34 of the Act, a rebuttable presumption of irreparable harm shall apply where there has been a finding of liability, or in the case of a motion for a preliminary injunction, a finding of probable success on the merits of the claim'. This means that the burden of proof then shifts to the defendant to disprove irreparable harm.

In the author's view, this approach may encourage trade mark bullying, and may be inconsistent with the public interest in freedom of competition and freedom of expression. Proving 'probable success' is not the same thing as proving liability for infringement or unfair competition, and could lead to cases where injunctions are issued without proof of any likely harm to the trade mark owner.

All that said, we do live in the real world, and in cases where the defendant's conduct is considered to be clearly wrong, perhaps even borderline outrageous, the Court may well decide that to apply too strict an approach to irreparable harm could put the Court in the position of siding with a wrongdoer. This was well expressed in Ludlow Music Inc. v Canint Music Corp. 1967 CarswellNat 19, a copyright decision of Jackett, P. of the then Exchequer Court of Canada, now the Federal Court of Canada. 'In effect, as it seems to me, it is a proper exercise of judicial discretion to protect property rights against encroachment that has no apparent justification, and, in particular, to protect copyright against what appears to be piracy.'

Albania Introduces New Trademark Regulation

Irma Cami, PETOŠEVIĆ Albania

A new trade mark regulation entered into force in Albania on 7 June 2018, clarifying a range of issues raised by the changes to the Albanian Industrial Property Law in force as of 24 March 2017. Some of the most significant changes and clarifications concern the following:

Clear Definitions and Representation Requirements

While the Albanian IP law defines a trade mark in general terms, the new regulation more clearly defines different types of trade marks as well as representation requirements for the most common traditional and non-traditional trade marks. It provides definitions for word, figurative, position, pattern, color and shape marks that are in line with the Implementing Regulation (EU) 2018/626 of 5 March 2018.

Having clear rules on trade mark representation enables applicants to clearly demonstrate the nature and features of their marks, which allows for proper examination and, at a later stage, adequate determination of the nature and scope of protection, especially in enforcement proceedings.

Literal Interpretation of Class Headings

The regulation adopts the literal approach when interpreting the scope of protection when class headings are used in lists of goods and services in trade mark applications and registrations. Namely, Article 13(2) of the regulation states that general terms, including class headings of the Nice Classification, are to be interpreted as including only the goods and services covered by the literal meaning of these terms.

This provision aligns Albanian legislation with that of the EU. Following the European Court of Justice 19 June 2012 decision in the IP Translator case, national IPOs in the EU moved away from the 'class heading covers all' to the 'means what it says' approach.

In the absence of a previous provision that provided otherwise, it is likely the Albanian authorities will apply this provision to both new and existing registrations. However, holders of existing registrations have so far been allowed to specify the list of goods and services intended to be covered when filing a renewal application, if they have not done so in their trade mark application. Therefore, applicants and holders of existing registrations are advised to clearly indicate whether they are seeking protection for all goods or services that fall within a particular class or only for the specific goods or services mentioned in the class heading, at the time of registration or renewal.

The regulation also introduces an interesting provision regarding the comparison of goods, namely Article 13(6) specifies that, when comparing goods or services, those covered by the same class should not necessarily be deemed similar, and those belonging to different classes should not necessarily be considered dissimilar. This is an improvement and a departure from previous practice, when the Albanian IPO often deemed goods or services similar or dissimilar solely based on their class.

Identical Marks

Article 22(8) of the regulation provides a definition of identical signs which does not limit the term to its literal meaning: 'signs should be considered identical where, when viewed as a whole, they are not differentiated, or contain insignificant differences.'
It seems that, when drafting this provision, the IPO took into account the definition from the decision in the Arthur et Félicie case.
http://curia.europa.eu/juris/liste.jsf?num=C-291/00.

Further, according to the regulation, the IPO can refuse a trade mark ex-officio if there is an earlier identical registered trade mark. This is in line with existing practice of the IPO. However, Article 143(2)(a) of the Albanian IP law provides for oppositions based on identity, rather than leaving the issue to the discretionary power of the IPO.

Unlike the law, the regulation also provides that the IPO can intervene ex-officio even when the goods designated by the identical marks are similar or related to each other. The regulation therefore significantly expands the definition of the identical mark, broadening the category of trade marks the IPO will be able to intervene in ex-officio. This may make the IPO decisions vulnerable to cancellation and create unsteady practice.

'Restitutio in Integrum' Procedure

The regulation clarifies the 'restitutio in integrum' procedure, which was introduced for trade marks, industrial designs and geographical indications following the IP law amendments in March of last year, while it has existed for patents since 2014.

Namely, an applicant who, for justified reasons and despite due diligence, failed to perform a certain action by a certain deadline, may request 'restitutio in integrum' if this failure resulted in loss of rights. This request must be filed within 60 days from the removal of the cause for non-compliance and no later than one year after the expiration of the missed deadline and is subject to the payment of a fee.

The IPO then examines the request within a month, and if the request is accepted, the IPO informs the applicant about the time period within which they should remedy the situation. If the request is refused, the applicant may oppose the decision before the IPO's Appeal Board within a month after receiving the written notification.

'Restitutio in integrum' does not apply to opposition and cancellation proceedings or to appeals against decisions in these proceedings.

Criteria for Determining Well-Known Marks

Article 58(1) of the regulation specifies that, when determining whether a mark is well-known, the Albanian authorities should take into account the Joint Recommendation Concerning Provisions on the Protection of Well-Known Marks adopted by WIPO in September 1999.

continued on next page

Albanian Trademark Introduction continued

Although Albanian authorities have already followed the Joint Recommendation in practice, having it specified as binding by the regulation will contribute to establishing steady practice.

However, the regulation failed to determine the procedure for establishing well-known status. It remains unclear whether it should be established in a separate procedure, or along with other claims, in court, or before the IPO.

Enforcement Procedures Held Before the IPO

Further to the March 2017 IP law amendments, the regulation establishes procedural rules for oppositions and cancellation actions held before the IPO. Under the amended IP law, the IPO will not only examine oppositions and appeals against refusals on absolute grounds, but will also handle other actions, including cancellation, invalidation and non-use actions and claims based on well-known status. The amended law also established two instances in the IPO, the first being the Examination Division and the second being the Appeal Board.

The regulation provides more time for the opponent and the applicant to respectively complete the file and respond to an opposition. It is now two months following the IPO's notification, whereas the previous regulation provided a shorter, one-month deadline.

While deadlines for enforcement cases cannot be extended or reinstated, the regulation enables claimants to act quickly. Namely, claimants can file a formal action by completing the standard form and paying the fee within the stipulated deadline, while they can file supporting documents and arguments within two months after receiving an invitation from the IPO to complete the file.

The Falsified Medicines Directive: the next 6 months

Rachel Havard and Julie Barrett-Major, A.A. Thornton & Co.

Directive 2011/62/EU, better known as The Falsified Medicines Directive or FMD, came into force on 2 January 2013, with the aim of preventing falsified medicines from entering the legitimate supply chain in the European Union.

Delegated Regulation (EU) 2016/161 has since supplemented FMD, setting out detailed rules for new safety features to appear on the packaging of prescription-only and some non-prescription medicines to enable them to be verified and authenticated:

- a unique identifier (a 2D data matrix code or barcode) is to be placed on product packaging, to be scanned at fixed points along the supply chain; and
- anti-tamper devices (ATDs) are to be applied to product packaging.

At each stage of the supply chain, products will be inspected to ensure they have not been tampered with, have not previously been dispensed and that the packaging is intact.

The Regulation will apply from 9 February 2019, and Marketing Authorization Holders will by then have to place the above safety features on the packaging of medicines regulated. These obligations are putting additional pressure on all in the pharmaceutical supply chain in the EU, not least parallel traders.

Parallel traders, who import medicines from lower-price into higher price markets, are considered 'manufacturers' under FMD, and will have to bolster their packaging and IT infrastructures.

To comply, when a parallel distributor receives packs of medicine from another EU country, they must first remove the unique identifiers and 'decommission' these packs from the country of origin's database. They must then re-package those medicines with new unique identifiers and ATDs, and re-commission them.

Although certain repackaging will not amount to registered trade mark infringement as established under EU case law, increased obligations upon parallel traders as a result of FMD could be a positive outcome for trade marks owners and their licensees. That said, packaging designs will need careful managing by parallel traders and originators alike, with additional features taking up space previously available for logos or distinctive get-up. This could reduce the opportunity for trade mark protection.

Brexit, set for 29 March 2019, adds uncertainty to the law and practice around parallel importing. The current UK Trade Marks Act (1994) effectively maintains a form of regional exhaustion applicable to the EEA. Unless or until a deal is reached with the EU, it is unclear whether the UK will remain in the EEA or in a relevant customs union with the EU. The UK Government suggests - in its 23 August 2018 guidance 'How medicines, medical devices and clinical trials would be regulated if there's no Brexit deal' - that 'the UK will unilaterally align to the EU/EEA exhaustion regime from Exit day to provide continuity in the immediate term ..' but as a 'temporary fix'. In the longer term, without amendment of the 1994 Act, the UK would revert to its pre-1973 position of international exhaustion, something that those supporting strong trade marks rights wish to avoid. Watch this space!

International Update

India

Samta Mehra, Remfry & Sagar

Glenmark sells an anti-fungal cream CANDID-B and filed a trade mark infringement suit against Galpha Laboratories on account of the latter's use of the mark CLODID-B, also for anti-fungal cream. The similarity was not just in the marks; Glenmark alleged the entire trade dress was near identical to its own product. Further, the current proceedings revealed that Galpha was a 'habitual offender' – previous instances were cited of its violation of Glenmark's trade mark rights as well as those of various other pharmaceutical companies.

Galpha did not contest the instant suit – it said its adoption of CLODID was a mistake and that it was willing to submit to a decree. 'Drugs are not sweets', the court said – pharma companies must exercise a high degree of care. Galpha was an 'audacious' repeat offender. Issuing it a 'final warning', the court imposed record costs of INR 15 million (USD $ 200,000 approximately).

Kosovo

Djurdja Krivokapić, PETOŠEVIĆ Serbia

The new Law on Customs Measures for Protection of Intellectual Property Rights enters into force in Kosovo on 23 May 2018 introducing important changes intended to align local customs procedures with Regulation (EU) No. 608/2013 concerning customs enforcement of IP rights.

Besides abolishing the annual EUR €100 (USD $118) customs watch application fee, the new law further streamlines the simplified procedure for the destruction of counterfeit goods and introduces the small consignments procedure.

According to the amended simplified procedure, rights holders are no longer required to send a cease and desist letter to notify the owner of the goods about the seizure and to seek consent for destruction. Instead, Kosovo Customs will notify both the rights holder and the owner about the detention within one working day. The rights holder will then have 10 working days to confirm whether the goods are infringing and consent to the destruction of the goods by sending a written notification to the Customs. In the meantime, the owner will also have 10 working days to agree or object to the destruction of goods. As under the previous law, if the owner does not explicitly object to the destruction, the Customs will destroy the goods (tacit consent). The goods will be released if the rights holder does not confirm that the goods are infringing or does not consent to the destruction, or if the owner of the goods has opposed the destruction and the rights holder has not filed a lawsuit within a maximum of 20 working days after the detention of the goods.

The new law introduces a new procedure under which small consignments (up to three units or weighing less than 2kg) can be destroyed without the explicit rights holder's consent. When filing a customs watch application, rights holders may opt in for this procedure, according to which, after seizing a small consignment, the Customs will inform the owner of the goods within one working day that it intends to destroy the goods. The owner then has 10 working days to either oppose the destruction or consent to it. If the owner agrees or fails to respond, the goods will be destroyed. If the owner opposes the destruction, the process is the same as in the simplified procedure.

The new law also clarifies that rights holders are:

- Required to inform the Customs that an IP right has ceased to have effect within one working day.
- Required to act according to the provisions of the simplified procedure. If they fail to do so, they must be able to provide a reason deemed appropriate by the Customs.
- Only allowed to use information provided to them by the Customs, such as information on the quantity and nature of the detained goods and contact details of the owner of the goods, for the following purposes:
  (1) to contact the importer to get consent for the destruction;
  (2) to initiate trade mark infringement or damage compensation proceedings; and
  (3) to initiate a criminal procedure. The use of such information in other ways could be considered misuse.

If rights holders fail to act as specified by the new law, they could face sanctions varying from monetary fines and revocations of customs watch applications to not being allowed to re-apply for customs watch for the IP right in question for a period of one year.

Laos

Denise Mirandah, mirandah asia

Laos's new Law on Intellectual Property No.38/NA of 15 November 2017 was published electronically in the Laos official gazette on 25 May 2018, and became effective 15 days subsequent to its publication. This supersedes the previous Law on Intellectual Property No. 01/NA dated 20 December 2011.

The new legislation brings reform to a variety of areas of intellectual property law in the country, but it is with respect to trade marks where the greatest number of amendments have been made.

A new digital platform is to be created which will publish submissions of new trade mark applications. Within 60 days of the publication of a new application, third parties can now oppose the registration of the mark concerned.

This is a fairly substantial innovation when compared to what means have been previously at the disposal of the third-party mark holder – solely cancellation. To achieve this, a cancellation request needed to be filed with the Department of Intellectual Property (DIP), which could only be done after the mark had been issued its trade mark certificate and registered – and within five years of the publication of said registration in the official gazette. Factoring in delays in the publication of registrations in the official gazette, this often meant that successful cancellation actions could only prevail after the mark had been put to use in Laos for a somewhat significant amount of time.

A further important amendment that the new law introduces relates to the term of protection of registered Laos trade marks. Trade mark registrations will now be valid for a period of 10 years following the filing date. Previously, marks had been valid for 10 years from the date of registration.

continued on next page

Lastly, the updated legislation also expands the range of matters which may be registered as trade marks in Laos. With the new law coming into effect, 3D images and animated images are now registrable.

It is anticipated that regulations will be issued in due course to supply further guidance to mark-holders on the scope and application of the new law. Given the extent of the changes introduced, time will need to be taken to develop infrastructure and train local officers in order to streamline registration and opposition procedures. Nevertheless, the introduction of the new legislation signifies a major step forward for Laos's trade mark regime.

Ukraine

Marina Maltykh, PETOŠEVIĆ

The IP-related provisions of the EU-Ukraine Association Agreement, signed and ratified by Ukraine in 2014, came into force on 1 September 2017, introducing new rules regulating the non-use grace period for trade marks. Namely, the existing trade mark law provides for a three-year non-use grace period, while Article 198 of the Agreement sets forth a five-year non-use grace period. However, Ukraine has not adopted any laws that implement such provisions in the national legislation and consequently, Ukrainian courts have faced a dilemma in non-use cancellation actions as to what the applicable grace period really is. This raised the question of direct applicability of the EU-Ukraine Association Agreement provisions, widely contested among Ukrainian IP professionals.

In a court ruling dated 12 February 2018 by the Commercial Court of Kyiv in the case no. 910/14972/17, the judge applied a five-year non-use grace period, as provided for under the Association Agreement (Art. 198), and rejected the non-use cancellation action, which was based on the three-year grace period, as per Ukrainian Trade Mark Law. The court held that the EU-Ukraine Association Agreement is a binding international agreement, thus its provisions should prevail and be directly applicable if they differ from the rules provided by the Ukrainian law. The ruling also emphasizes that the Association Agreement does not foresee any particular means of implementation of these provisions in the Ukrainian national law. This ruling was appealed before the Kyiv City Commercial Court of Appeal, which affirmed the judgement of the Commercial Court of Kyiv on 23 April 2018. The case ended up reaching the Ukrainian Supreme Court, which upheld the decisions of the lower courts on 17 July 2018. While the Supreme Court's arguments were similar to those of the Commercial Court of Kyiv, it did not explicitly address the issue of direct applicability of the Association Agreement.

In the debate surrounding this issue, one of the arguments against the Agreement's direct applicability considers the subjects to whom it is addressed. Namely, Art. 198 of the Association Agreement states that 'the Parties shall provide that a trade mark shall be liable to revocation if, within a continuous period of five years, it has not been put to genuine use...' The majority of the Agreement's other provisions are also addressed to the parties of the Agreement, not legal entities and individuals, which leads to the conclusion that these provisions are not self-executing and require further implementation into national legislation. In fact, the Cabinet of Ministers submitted to Parliament a draft law implementing the provisions of Art. 198 into the Ukrainian Trade Mark Law on 23 January 2017, proving the Government's intentions to take additional steps to implement the Agreement's provisions into the local law. However, this law has not yet been adopted.

While the cassation appeal brought before the Supreme Court in case no. 910/14972/17 mentioned the Association Agreement implementing measures contained in the Resolution of the Cabinet of Ministers No. 847 of 17 September 2014 'On the Implementation of the Agreement' and in the explanatory note to the draft law 'On Ratification of the EU-Ukraine Association Agreement', the Supreme Court ruled that these were not regulatory legal acts, and that such measures did not prevent commercial courts from applying the Association Agreement's provisions when considering this dispute. Therefore, the Supreme Court de facto ruled on the direct applicability of the EU-Ukraine Association Agreement.

Art. 198 of the Association Agreement seems to be the only provision of the Agreement which has been so far directly applied by courts. For instance, courts, including the Supreme Court, have been applying provisions of Art. 52 of the Ukrainian Law 'On Copyright and Related Rights' when regulating the compensation amount for the infringement of copyright and related rights, in spite of Art. 240 of the Association Agreement foreseeing a different mechanism of compensation. In fact, a law implementing the modified provisions of Art. 240 of the Agreement came into force on 22 July 2018.

The cassation appeal referenced the provisions of the Decree of the Cabinet of Ministers No. 15-93 of 19 February 1993, which require obtaining licenses for some operations with currency and which are actually applied in practice, as opposed to Art. 145 of the Association Agreement, which provides for the free movement of capital. The Supreme Court however ruled that this reference was inappropriate because the mentioned provisions do not regulate the dispute in question.

The appellant also claimed that applying provisions of Art. 198 in this case would set a precedent with negative consequences, but the Supreme Court ruled that the Ukrainian legal system does not recognize judicial practice as a source of law. However, in accordance with Art. 13 of the Ukrainian Law 'On the Judicial System and the Status of Judges', the Supreme Court's conclusions regarding the application of the rules of law are to be taken into account by other courts when applying such rules of law.

In conclusion, while on the one hand the Supreme Court's ruling ends the long-term debate on what the non-use grace period in Ukraine actually is, on the other hand it still raises a number of issues that remain vague. It appears that only further case law may clarify the issue of the EU-Ukraine Association Agreement's direct applicability. However, this case should be taken into account when filing a non-use cancellation action in Ukraine.

Italy – Parallel imports of medical devices: a landmark decision, a manufacturers' win.

Laura Pedemonte, Barzanò & Zanardo

Although there is plenty of case law from both the European Court of Justice (ECJ) and the EU national Courts on the parallel import of drugs, very few decisions exist regarding the parallel import of medical devices. The Court of Milan recently issued a landmark ruling in a case relating to the parallel import of home-self monitoring medical devices whose repackaging was challenged by the trade mark holder.

Facts

The multinational Johnson & Johnson (J&J) has been marketing in Italy a glucose home-control device in packages containing either 25 or 100 strips under the registered EU trade mark ONE TOUCH ULTRA.

The product was also commercialized by J&J in other EU countries in packets of 25, 50 or 100-strips.

In 2013, the parallel importing company, Medifarm Srl (Medifarm) operating in Italy and abroad, purchased J&J's ONE TOUCH ULTRA devices in 50-strip packages in another EU country and started to market them in Italy, after repackaging in packs of 25 or 100-strips.

In 2014, J&J promptly started preliminary injunction proceedings before the Court of Milan claiming, inter alia, trade mark infringement, alleging (i) the lack of any actual need to repackage the device and (ii) that the repackaging was justified only by Medifarm's attempt to secure a commercial advantage.

Medifarm, for its part, contended that the repackaging was necessary (i) to gain access to the Italian market and (ii) to benefit from the reimbursement provided by the National Health System for the purchase of 25 or 100-strip packets only.

In 2014, the Court of Milan, referring to EU case law (in particular, C-379/97- Upjohn, and C-348/04 Boehringer Ingelheim and Others), decided to provisionally seize the contested devices deeming that Medifarm had not demonstrated that the repackaging was strictly necessary. In fact, the Court observed that the Defendant could have purchased and imported, without any need to repackage, the 25 or 100-strip packets available in many other EU markets.

Following the above interim relief decision, J&J commenced the law suit against Medifarm, where the parties' arguments were substantially the same. In addition, the Defendant asked the Court of Milan to refer to the ECJ the issues whether (i) the principles as in ECJ case law (the so called 'BMS/Boehringer' conditions) could apply to this medical device repackaging case, (ii) and, if so, how it would be applicable to the subject issue.

Decision

In a decision dated 13 December 2017, the court of Milan upheld all J&J's claims, deeming Medifarm's repackaging illicit pursuant to Art. 15 of the EC Directive No. 2015/2436 (former Art. 7 of EC Directive No. 2008/95), for the following reasons:

(1) The criteria stated by the ECJ can apply to this medical device repackaging case: there is no need to refer the issue to the Court considering its solid case law on the principles concerning the justified repackaging of drugs;

(2) In particular, the ECJ stated that the repackaging is necessary when the size of the packets used by the trade mark owner in the exporting Member State could not be marketed in the importing Member State because of, in particular, national rules permitting packaging of a certain size only, a national practice to the same effect, or well-established medical prescription practices based on, inter alia, standard sizes recommended by medical professional and medical insurance institutions (ECJ decisions in joined cases Bristol-Myers Squibb and Others v Paranova);

(3) This was not the case, considering that there was no entry barrier to market the 50-strip packs. In fact, it was proved that Medifarm had also successfully marketed in Italy the 50-strip packs and not only the 25 or 100-strip packets and, in any case, the latter packets were available in other EEA countries. The Court of Milan cited, in particular, the recent ECJ decision C-297/15 - Ferring Lægemidler v Orifarm

http://curia.europa.eu/juris/liste.jsf?num=C-297/15

Comments

This decision is relevant for the following aspects.

(1) Firstly, because it confirms the trend of our Court's, basically restrictive interpretation of justified repackaging. The reason for our Courts' position can be found in the particular caution given to the protection of both manufacturers and consumers regarding tampering of products with a direct link to health. For such sensitive goods, guarantee of origin, sterility and reliability are of great importance because of the high degree of responsibility of the producers and the particular attention customers pay towards their own health.

(2) Secondly, because it is one of the few decisions of the EU Courts on the topic of parallel imports of medical devices and necessary repackaging and the first ruling in Italy on this subject issued in ordinary proceedings. This decision was anticipated by two orders of 21 September and 20 October 2009 (Roche Diagnostic v BB Farma Srl) issued by the Court of Milan in the framework of preliminary proceedings and again in favour of the trade mark owner.

continued on next page

continued from previous page

(3) Last but not least, the subject decision is also important because the Court of Milan applied ECJ case law and principles in connection with parallel import of pharmaceutical products to medical devices. The Court did not provide specific reasons for this extension other than referring to the solid case law on repackaging of drugs.

Actually, the fact that the application of those principles is not restricted to cases of parallel importation of pharmaceutical products was affirmed by the ECJ in its 11 November 1997 Loendersloot judgment. In said case, the Court held that the criteria relating to the repackaging of pharmaceutical products could also, in principle, apply to parallel trade of alcoholic beverages.

We may assume that, all the more so, the above criteria have been deemed applicable in the case of medical devices considering their clear analogy with pharmaceutical products.

The issue of the extension of the ECJ BMS/Boehringer conditions to medical devices has been very recently raised in Junek Europ-Vertrieb case. The Court of Justice, in its decision of 17 May 2018, did not take position on this specific matter but made reference to said principles in connection with a case of relabelling of medical devices. By excluding the applicability of the BMS/Boehringer conditions provided for cases of repackaging to the specific case of addition of a small label on medical device packs, the extension of said principles to cases of repackaging of medical devices could be indirectly inferred.

The topic of parallel imports of medical devices appears to be in the spotlight, most likely due to the increasing importance of this market. It will be interesting to see whether other EU national Courts' decisions on the matter will follow and whether the Court of Justice will be called to take position on cases of justified repackaging of medical devices. Meanwhile, this case is an important win in favour of the manufacturers in the never-ending battle against importers.

PANADOL v ZANAMOL

Chris McLeod & Luke Ingleton, Elkington + Fife

The United Kingdom Intellectual Property Office (UK IPO) has dismissed an opposition by GlaxoSmithKline Consumer Healthcare (UK) IP Limited (GSK) to an application for ZANAMOL in class 5.

Background

In October 2016, Apollo Generic Limited (Apollo), a pharmaceutical company specialising in prescription pharmaceuticals and over-the-counter medicines, filed a UK application for a series of two marks, ZANAMOL and Zanamol. When published, GSK opposed the application on the basis of its earlier European Union Trade Mark (EUTM) registration of PANADOL in class 5. GSK argued that there was a likelihood of confusion between the marks.

The decision

To assess the likelihood of confusion, the IPO's Hearing Officer (HO) first compared the respective goods. In its counterstatement, Apollo had admitted that some of the class 5 goods covered by its application were identical and/or similar to the goods in the specification of GSK's earlier registration. Having compared the remaining goods and considering the relevant factors, including method of use, users of the goods, physical nature of the goods and trade channels, the HO found that the respective goods were similar. The HO then considered the average consumers for the goods. As the goods were pharmaceuticals and medical preparations, the HO found that the average consumers were pharmaceutical / healthcare professionals, in addition to members of the general public, all of whom pay a reasonable to high degree of attention when purchasing the goods.

Comparison of the marks

Although the ZANAMOL and PANADOL marks consist of seven letters and coincide in the letters A-N-A-O-L in the same order, the HO found that the marks were visually and aurally similar only to a low degree. The HO emphasised that the striking difference at the beginning of the marks and the attention that consumers pay to the beginning of a mark were key factors when conducting the comparison of the marks. The HO found the conceptual comparison of the marks to be neutral.

The HO also held that the PANADOL mark enjoyed a level of enhanced distinctiveness because of evidence of use of the mark in the UK since the 1950s and because of such evidence PANADOL was one of the biggest selling brands of paracetamol-based pain relief. This is an important factor in the global appreciation of the likelihood of confusion because the more distinctive the earlier mark, the greater the likelihood of confusion with the mark applied for.

Having considered all of the relevant factors, the HO concluded that there was no likelihood of confusion between the marks because the differences far outweighed the similarities. Accordingly, the HO found in favour of Apollo and ordered GSK to pay costs.

Comment

This decision highlights the emphasis placed on the differences at the beginning of marks being compared, particularly in circumstances where the marks are used on goods or services to which the average consumer pays a high degree of attention when making purchasing decisions. Perhaps if GSK had also based the opposition on damage to reputation, the outcome may have been different.

PROFILE: Chris McLeod

Chris McLeod is a Chartered Trade Mark Attorney and a Fellow of CITMA, the Chartered Institute of Trade Mark Attorneys, of which he was President from 2014 to 2016 and in which he is still active. Chris has practised in trade marks, designs and related IP issues for over 30 years. He has been an active member of PTMG since around 2000, his first PTMG conference being in Marrakesh, and has attended many of PTMG's conference since then. He is also a member of INTA and a regular speaker and commentator on trade mark issues.

Where were you brought up and educated?

I was born in Hampshire, but soon moved to Cyprus, then to Derbyshire, Wiltshire and South Wales, all by the age of 10. At that point, I went to boarding school at Christ's Hospital in West Sussex (Google it to see the uniform), followed by the late lamented Bedford College which was part of the University of London.

How did you become involved in trade marks?

Through foreign languages. I studied French and German at university, failed to become an interpreter, then found a job at the Job Centre on High Holborn in London, working for Trade Marks Directory Service (TMDS, now part of CPA Global), conducting manual trade mark watching and translating specifications of goods and services.

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

I have always loved music and comedy, so perhaps a singing comedian, although my wife claims I cannot sing in tune and is even less complimentary about my jokes.

Which three words would you use to describe yourself?

Reliable, pedantic, optimistic.

Complete the following sentence. "I wish ...."

....that Brexit was not happening.

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

French and German.

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

...wrapping presents.

What do you wish more people would take notice of?

Climate change / global warming.

What's the best thing about your job?

Every day brings different challenges. Meeting those challenges and giving clients a prompt commercial response brings a sense of achievement.

If you weren't completing this interview, what would you be doing right now?

Threatening to oppose a trade mark application.

What is a common misperception of you?

That I tell bad jokes.

What is your philosophy in a nutshell?

Life should be fun, so only take things seriously when necessary.

Which book or books are you currently reading?

'Sticky Fingers: The Life and Times of Jann Wenner and Rolling Stone Magazine' by Joe Hagan and 'Dead Man's Footsteps' by Peter James.

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

It would have to be Arkology by Lee Perry. More versions of Police and Thieves than you could shake a stick at.

Which sport do you play and/or enjoy?

Football/Soccer. I still play twice a week, although I understand that I should have taken up golf by now. I am also a lifelong fan of Derby County and am convinced that they will rise into the English Premier League again soon.

Which is your favourite restaurant?

At the moment, it's a tie between Anglo in Farringdon and Canaletes on Willesden Lane (north west London).

What is your favourite drink?

Wine – white: Picpoul de Pinet (French), red: Gift Horse (South African).

What is your favourite holiday destination?

New York City.

If you could enact one law, what would it be?

Spot fines for people playing Candy Crush with the sound on whilst on public transport.

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

The High Line in Manhattan. The way it has turned a disused elevated rail line into a destination with amazing views, architecture and planting is just stunning. It is always on my list of places to revisit.

© 2018 The Pharmaceutical Trade Marks Group
Circulated for information only to PTMG Members. The Group takes no responsibility for the contents
Editor: Vanessa Parker
Tel.: +33 679 316 860 email: vparkercordier@wanadoo.fr