

# Law Lore & Practice

PTMG



Pharmaceutical  
Trade Marks Group

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## Editorial: a Brave New World © A. Huxley

Writing this in between the two rounds of the French Presidential elections and watching the United Kingdom struggle with yet another electoral process, I have decided to adopt Aldous Huxley's approach and look far into the future. His novel, written in 1931, was set in the year AD 2540 and is still considered a

masterpiece of the science fiction genre. The technological advances referred to in this Editorial have not, in some cases, and should not, in others, wait until that date to be accessible to all those who need them.

The very recent announcement by the Children's Hospital of Philadelphia of the creation of an artificial womb mimicking the prenatal fluid-filled environment for premature babies born at 23/24 weeks gestation opens up the possibility that current incubator and ventilator solutions will ultimately be replaced. Meanwhile, insulin pens already help diabetes sufferers with replaceable pen needles which have become extremely discreet and easy to use. Research & Development in this field continues to look at pre-empting the drop in sugar levels as opposed to injecting once the sugar level has dropped.

Quality of life is what we all aspire to, whatever our elected representatives try to do with our everyday lives. A leading Japanese industrial automation pioneer has launched PARO®, the 8th generation of an advanced interactive robot whose earlier versions have been used throughout Europe and in Japan since 2003 and which is designed to help those who need end of life care. Its use in hospitals and care homes have already produced surprising results and provides much needed support to patients, their families and health care professionals. In another medical field, genetic scissors, also known as the molecular scalpel, are descriptive terms employed to describe the process of a new method of gene editing which, let us remember, was a practice unavailable just a generation ago.

The recent March for Science which took place on 22nd April in more than 600 cities across the world on Earth Day, gives us all hope that whatever happens in the next few months, we must continue to aspire to push back the boundaries of knowledge and encourage our children to look towards their future.

Vanessa

## US Update

Jonathan S. Jennings, Pattishall, McAuliffe [1]

On 27 February, 2017, the US Supreme Court denied Belmora LLC's petition for a writ of certiorari in the case *Belmora LLC v Bayer Consumer Care AG and Bayer Healthcare LLC*, 84 F. Supp. 3d 490 (E.D.Va. 2015), vacated and remanded, 819 F.3d 697 (4th Cir. 2016), cert. denied, No. 16-548, 2017 WL 737826 (US 27 Feb., 2017). The case has now been returned to the United States District Court for the Eastern District of Virginia and proceedings have resumed this month.

The case, originally reported on last year, involves Bayer Consumer Care's sale of a pain reliever in Mexico under the trade mark FLANAX. Bayer does not have a US trade mark registration of FLANAX and does not sell FLANAX branded products in the US. In the US, Bayer markets a comparable naproxen sodium pain reliever under the trade mark ALEVE. Without Bayer's authorization,

Belmora LLC began selling a naproxen sodium pain reliever in the US under the FLANAX mark, in the same trade dress as Bayer's Mexican FLANAX, and registered the FLANAX mark with the United States Patent and Trademark Office (USPTO). Bayer brought a cancellation proceeding in the USPTO, which was successful. Both parties then brought suit in federal court over the USPTO's decision and related issues, during which Belmora continued its use and promotion of FLANAX in the US.

The Supreme Court's decision not to take the case is significant because it means that the Fourth Circuit's 23 March, 2016 opinion stands, and continues as precedent for the proposition that brand owners need not own or use a trade mark in the United States in order to have standing to bring a federal suit for unfair competition in cases of

misrepresentation.

The issue before the district court now is whether Belmora's conduct constitutes passing off, unfair competition or false advertising, and whether the USPTO's decision to cancel Belmora's FLANAX registration on the basis of misrepresentation should be upheld. In the original decision, the court did not reach these ultimate issues, but merely decided whether or not Bayer's claims were legally valid if proven.

This case should be watched closely for guidance on precisely what constitutes actionable misrepresentation and passing off in situations where a brand owner does not own or use a trade mark in the US, but does in another country.

[1] Members of the author's firm represent Bayer in this case.



Paris in Springtime - what an iconic and peaceful pleasure! While the world at the beginning of the year 2017 seems to be full of unrest and turmoil, we have started the year with another wonderful PTMG conference in Paris. The city was as spectacular and welcoming as ever and even the weather was pretty fantastic (it was very expensive to arrange for that!) when we went there for our spring conference. It was wonderful to return to Paris where we had not been for such a long time. I very much enjoyed the typical French hospitality, elegance and cuisine and I have noticed that it seems to be very trendy these days to decorate about every dessert with plenty of gold foil (probably invented at the court of Louis XIV). The venues were spectacular, especially the restaurant Le Train Bleu where we had our optional dinner. I must admit that in Germany railway station restaurants are by far less breathtaking.

The conference room of the Grand Hotel enchanted us with its Versailles like flamboyant splendor. The speakers did very well and got our full attention. Again we saw a whole bouquet of interesting IP topics from all over the globe. The feedback we have received for both the speakers and the topics was very positive. Thanks a lot for that!

As you know our Autumn conference will be held in Toronto in October and registration for that starts in June. I hope to see many of you there. Until then I wish all of you a nice and peaceful summer season.

**Frank Meixner**

## Members News

### New Members

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

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### Moves and Mergers

Following **Bob Lee's** retirement from Eli Lilly and Company, Bruce Longbottom has taken over as Head of Lilly's Trade Mark Department in Indianapolis, USA. Bruce can be contacted at [Longbottom\\_bruce@lilly.com](mailto:Longbottom_bruce@lilly.com)

**David Stone** has left Simmons & Simmons to join Allen & Overy LLP, London, UK. David can now be contacted at [david.stone@allenoverly.com](mailto:david.stone@allenoverly.com)

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**Alistair Payne** has left Matheson to set up his own firm called Actuatius in Dublin, Ireland. Alistair can be contacted at [alistairpayne@actuatius.com](mailto:alistairpayne@actuatius.com)

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**Lesley Edwards**  
PTMG Secretary

# Flynn prevents parallel imports

**Cassandra Hill, Mishcon de Reya LLP**

The Court of Appeal has decided that a trade mark owner can prevent the parallel importation of pharmaceutical products sold under their trade mark in circumstances where the trade mark owner had neither consented to nor put the parallel imported goods on the market.

This case develops the law on parallel imports in a situation where the relevant goods were not put on the market by the trade mark owner, but by a third party, and focuses on the issue of 'control'. 'Control' (certainly on this set of facts) is material as to whether the trade mark owner can prevent the particular parallel imports. The Court concluded that Flynn (the trade mark owner) did not have the ability to exercise control over the goods before they were placed on the market by Pfizer in the exporting state. Further, the links between Flynn and Pfizer were not such that use of the Flynn trade mark was under Pfizer's control. Accordingly, Flynn's enforcement of its trade mark against parallel imports of products manufactured by Pfizer, and bearing Flynn's mark, would not breach free movement of goods provisions.

## Background

In 2012, Flynn Pharma acquired from Pfizer the UK marketing authorisations for an anti-epileptic drug, whose international non-proprietary name (INN) is phenytoin sodium, but which Pfizer sold under the brand Epanutin. Flynn's intention was to genericise the drug in the UK which meant removing the Epanutin branding and selling the drug by reference to its INN. Flynn applied to the MHRA to change the name to Phenytoin Sodium. As this would remove the drug from the pharmaceutical price regulation scheme, genericising the drug allowed Flynn to increase the price.

The drug has a narrow therapeutic index which means that the level of the drug in a patient's blood stream is crucial – even a small change in the blood level could render the drug ineffective or toxic. Because of this issue, the MHRA declined to permit Flynn to use simply phenytoin sodium, but said that the product should be called Phenytoin Sodium Flynn. This would ensure patients would know they were taking the same drug as previously prescribed and would avoid problems of being unable to distinguish between drugs from different sources which might have subtle differences (which, given the drug's narrow therapeutic index, could cause serious effects on the patient). Flynn obtained a UK and an EU trade mark for FLYNN.

The appellants, DrugsRUs and Tenolo, trade in parallel imported pharmaceutical products. They sought to import phenytoin sodium which Pfizer had put

on the market as Epanutin in other EU member states. The appellants sought to market the imported product as phenytoin sodium in the UK. The MHRA objected and said it should be marketed under the name under which the UK product is marketed i.e., Phenytoin Sodium Flynn, or Epanutin as the name of the product in the source country (albeit this option presented the appellants with a number of issues). As a side note, when giving such guidance, the MHRA takes no account of intellectual property rights. On being notified of the appellants' intention to market the drug in the UK under Phenytoin Sodium Flynn, the company Flynn issued proceedings for trade mark infringement. The High Court held that applying the sign Phenytoin Sodium Flynn to imports of the drug into the UK from other EU member states would infringe Flynn's trade marks.

The appellants appealed on the basis that, amongst other things, the decision breached EU rules on the free movement of goods, as enforcement of Flynn's trade mark constituted a disguised restriction on trade between EU member states. EU law on free movement of goods Article 34 of the Treaty on the Functioning of the European Union (TFEU) provides for free movement of goods within the EU.

Article 36 TFEU provides some exceptions to this principle including prohibitions or restrictions on imports justified on the grounds of protection of industrial and commercial property, including protection of trade mark rights. However, such restrictions cannot be enforced if they constitute 'a means of arbitrary discrimination or a disguised restriction sometimes called an artificial barrier on trade between member states'.

Therefore, whilst there may be cases where enforcement of a trade mark may be justified, such enforcement can be prohibited in certain circumstances if it amounts to a disguised restriction on inter-member state trade.

## Court of Appeal decision

The Court of Appeal concluded that:

- Flynn had a legitimate interest to enforce their trade mark against goods which had never been placed on the market by them under their trade mark and over which they had no control.
- Sales of Pfizer's imported product by the appellants under the sign Phenytoin Sodium Flynn would affect the guarantee of origin which Flynn's trade mark entailed. Further, the appellants would be taking advantage of the reputation of Flynn's trade marks in selling such parallel imports.

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# International Update

## HUNGARY

### PETOSEVIC

On 22 November, 2016, Hungary adopted a new Civil Procedure Code (CPC), to enter into force on 1 January, 2018.

Legislators reintroduced the divided civil procedure which was cancelled in 1952. Namely, civil procedure will be divided into the preparatory stage and the negotiation stage. In the preparatory stage, the parties will have to present all facts, reasons and evidence relevant to the case, and will be able to modify their claims and file a defense. The court will have the option to extend the preparatory stage due to a lack of evidence, and if the parties file their offers of proof too late, the court may impose a fine as the ultimate sanction in order to avoid delays. The preparatory phase will enable the court to clarify the content of a dispute and will facilitate the decision-making process in the negotiation phase.

Furthermore, the new CPC introduces the 'private expert' concept, meaning that, if a professional aspect of the case has to be examined, the party may decide whether to request a state expert's opinion or private expert's report.

The new Code also enables the Court of Appeal to request additional evidence in order to avoid returning cases to the court of first instance, as it now has to decide based only on the evidence submitted to the first instance court.

As for exceptional remedies, it is currently possible to file a motion for reconsideration in any type of case. The new CPC, on the other hand, states that a motion for reconsideration may be submitted only if the subject matter of the dispute is worth over EUR €16,135 or if the court considers a revision necessary due to significant social interest or to ensure the uniformity of decisions.

## INDIA

### Isha Mital, Chadha & Chadha

A Full Bench of the Bombay High Court, in its recent judgment *CIPLA Limited v M/s CIPLA Industries Private Ltd*, shed considerable light on the use of a registered mark in another entity's corporate or trade name, with respect to dissimilar goods and services.

The mark *CIPLA* had been used by the plaintiffs, for numerous years, and was part of their corporate and trade name. It had been used for medicinal and pharmaceutical preparations, largely in Class 5. The defendants used the name *CIPLA* as part of their corporate or trade name, and in a slightly different form in respect of household articles. The defendants also possessed a registered mark *CIPLA PLAST*, in their favour, in

Class 21.

Under trade mark law in India, infringement may be found in cases where, inter alia, the mark is identical with or similar to an earlier trade mark for dissimilar goods and services; as also for the use of the mark as a corporate name for similar goods and services. An earlier decision of the Bombay High Court *Raymond Limited v Raymond Pharmaceuticals Pvt. Ltd*, held the field, which had applied the principle of *generalia specialibus non derogant* (a general provision must always yield to a specific provision), holding that sections dealing with the use of a registered trade mark as part of a corporate or trade name, for the same goods and services in respect of which the mark had been registered (S. 29(5) of the Trade Marks Act), would take precedence over other sections dealing with infringement (S. 29(4)). In the *Raymond* case, since the goods and services in question were dissimilar, no infringement had been found.

The Single Judge bowed to the decision in *Raymond*, but read down the order to indicate that a proprietor may use his mark either as a mark, or as a corporate name. The proprietor may succeed in an infringement suit if the defendant uses the mark as a mark for similar or dissimilar goods, or as a corporate name for similar goods. In *Cipla*, the defendant had used the Plaintiff's registered mark as a corporate name, for dissimilar goods.

### The Full Bench

The Full Bench held that the language of the act was clear and unambiguous. In order for infringement to be found (in the facts of the case) the mark is to be used as part of the trade name, and in respect of the same goods and services in respect of which the trade mark in question was registered.

The Full Bench thus conclusively held that there is no cause for infringement when the registered mark is used as a corporate/trade name in respect of dissimilar goods and services.

While this decision will keep larger entities from unfairly preventing others from using marks in good faith, as well as protect the rights of bona fide concurrent users, it does not entirely protect the rights of the proprietors of well known marks. Since S. 29(5) (dealing with use of the mark in a corporate name) is in the nature of a 'no-fault provision', requiring only that the conditions inherent therein are fulfilled, there is no requirement for likelihood of confusion to be proved. Therefore, under S. 29, it may prove difficult for proprietors of marks to prove infringement where their own mark is used in the traditional sense of a mark

- Enforcement of the trade marks against the parallel imports did not amount to a disguised restriction on trade between member states. In reaching its conclusion, the Court of Appeal considered that the case required a dual enquiry:

- Firstly, were the goods which the alleged infringer wanted to import goods placed on the market by the trade mark owner or with his consent?
- Secondly, even if the answer was no, was the party who did place the goods on the market under a trade mark also in effective control of the trade mark sought to be enforced?

The Court of Appeal considered that, if the answer to both questions was no, then it was difficult to see how enforcement of the trade mark could be anything other than designed to protect the origin function of the trade mark – there would be no artificial barrier to trade because the trade mark would be being enforced in a justified manner to safeguard its origin function.

On the first enquiry, the Court of Appeal found that:

- Flynn had not placed the goods on the market in the EU; Pfizer had.
- Flynn and Pfizer were entirely separate companies with no corporate links and Flynn had no control over the quality of the Epanutin put on the market in other EU member states by Pfizer (albeit Flynn had control of the product Pfizer sold to Flynn but that was a separate issue).
- The fact that the parallel goods were from the same source as Flynn's goods was not equivalent to Flynn giving consent to the marketing of such goods or having control over their quality. Pfizer placed those goods on the market and controlled their quality independently of Flynn.

On the second enquiry, the Court of Appeal found that:

- The arrangements between Pfizer and Flynn were arm's length transactions between independent companies.
- Flynn could put its own trade mark on the product and Pfizer had no control over that.
- The trade mark applied to the goods as an indicator of the origin of control had no connection with Pfizer. Pfizer was not able to use that mark in respect of any goods other than those it made under agreement for Flynn, and Pfizer could not change any aspect of the manufacture of those goods without Flynn's consent.

It is understood that *DrugsRUs* intends to seek permission to appeal to the Supreme Court.

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# International Update continued

and the other party uses it as part of their trade or corporate name, and where the goods and services as covered by both marks are not similar.

## MONTENEGRO

### PETOSEVIC

The amended laws on patents, trade marks and industrial designs entered into force in Montenegro on 18 January, 2017. Most amendments relate to terminology alignment with the new Law on Administrative Proceedings, but there are two other significant changes.

All three laws introduce administrative disputes against the Montenegro IPO decisions. Under the former laws, the Montenegrin Ministry of Economy had competence to rule in the second instance and further appeals were brought before the Administrative Court. The amended laws abolish this practice after 6 years of being in force. Now, appeals are to be brought directly before the Administrative Court.

The reason behind this change is the complexity of the registration process, particularly in terms of trade marks, where reaching a decision often requires expert knowledge of examination practices and thorough analysis.

A similar practice of appealing IPO decisions directly before the courts is also applied in some EU countries, like France and Ireland.

Another novelty in the amended Law on Trademarks is the possibility for parties to suspend a trade mark opposition proceeding while negotiating an agreement. The parties have to reach an agreement within 6 months.

Requesting a suspension was previously possible under the provisions of the Law on Administrative Proceedings. However, the amended Law on Trademarks now clearly defines the parties' obligations in such situations. If the parties realize they will not reach an agreement within 6 months, they can request the continuation of the proceeding. If no agreement is reached within these 6 months and the negotiations continue, the parties have to compose minutes of their negotiations and communicate them to the IPO.

## TURKEY

### Selma Ünlü, NSN

#### Background

Novartis AG (Novartis) developed a human monoclonal antibody named CANAKINUMAB which is commercially marketed as a pharmaceutical product under the ILARIS trade mark. CANAKINUMAB was recognized as an international non-proprietary name (INN) by the World Health Organisation (WHO) meaning that it constitutes an identification of a pharmaceutical active

ingredient that falls within the public property. According to WHO, trade marks should neither be derived from INNs nor contain common stems used in INNs.

In 2014, Novartis identified an application by a third party before the Turkish Patent and Trademark Office (TPTO) for registration of CANMAB in Class 05 covering pharmaceutical combinations and preparations. Novartis duly filed an opposition against the application under Article 7(1)(a), 7(1)(c), 7(1)(d), 7(1)(f) and 7(1)(k) of the Decree Law Regarding Protection of Trademarks all of which regulated the absolute grounds of refusal. Novartis argued in detail that a trade mark which includes the stem of an INN and is also confusingly similar to an INN in overall comparison cannot be registered as a trade mark. The trade mark examiner refused the opposition.

Novartis appealed the refusal decision of the trade mark examiner before the Re-Examination and Re-Evaluation Board (REEB) of TPTO by mainly arguing that the CANMAB trade mark application fell within the scope of Article 7 and cannot be registered under the principles of WHO regarding INNs.

#### Decision

In the appeal, Novartis initially emphasized that the CANMAB application included the INN stem of -mab which is contained in several INNs recognized by WHO such as CANAKINUMAB, CANTUZUMAB, TEPLIZUMAB, FARLETUZUMAB, ELOTUZUMAB, RONTALIZUMAB. The appeal focused on the general principle of WHO requiring that the trade marks containing INN stems cannot be registered. Novartis relied on the previous decisions of Turkish courts and REEB which explicitly accepted that an INN stem cannot be registered as a part of a trade mark.

Novartis further relied on the second principle of WHO setting forth that trade marks which are derived from INNs should not be registered as trade marks. Accordingly, it was emphasized that the CANMAB application did not only include the -mab stem but was also confusingly similar to the CANAKINUMAB and CANTUZUMAB INNs, both of which started with CAN and ended with MAB letters. Novartis discussed in detail that the CANMAB application was clearly derived from these INNs in a manner causing likelihood of confusion which would trigger serious negative consequences on patient health and safety.

Finally, Novartis put forward arguments on the reasons why CANMAB should not be registered as a trade mark under each sub-paragraph of Article 7.

Upon examination of the appeal, REEB reversed the trade mark examiner's decision and decided that the CANMAB application cannot be registered as a trade

mark since it was found to be descriptive and lacking distinctiveness due to the fact that the applied trade mark:

- included the '-mab' stem which is contained in several INNs recognized by WHO,
- is likely to be confused with the CANKINUMAB and CANTUZUMAB INNs as they have the CAN and MAB parts in common.

#### Comment

Novartis successfully challenged the trade mark examiner's refusal decision and prevented registration of CANMAB in Class 05. Within the established practice of TPTO, although trade mark examiners have been frequently refraining from accepting oppositions on the basis of INNs, most of the recent decisions of REEB have reversed this tendency. The decision granted by REEB in this CANMAB matter is particularly important as it does not only acknowledge the requirement to protect INN stems in accordance with the precedents of TPTO and courts but it also accepts that trade marks which are likely to be associated with an INN cannot be registered as a trade mark either.

## VIETNAM

### Linh Thi Mai Nguyen, Tilleke & Gibbins

Vietnam's IP laws and regulations do not mention INNs. Indeed, in 2007, the Drug Administration of Vietnam issued Official Letter No. 2284 mentioning the WHO's guidelines on INNs and requested Vietnam's Trademark Office (the National Office of Intellectual Property, or NOIP) to help prevent the registration of trade marks derived from INNs or containing INN stems. However, official letters are not considered legal normative documents under Vietnam's laws; therefore, Official Letter No. 2284 is not considered as having legal binding effect.

In practice, the NOIP does not actively search for INNs when examining trade marks for pharmaceutical products. There have not been any precedents where marks were rejected/invalidated in Vietnam for deriving from INNs or their common stems. On the contrary, there are actually many trade marks that are derived from INNs or contain common stems that co-exist in the trade mark registry. This may cause confusion to consumers, not only between the trade marks themselves, but also between the trade marks and the INNs.

Nevertheless, for the ultimate goal of protecting the consumers'/patients' health and interests, it is expected that the NOIP will soon follow the global trend. As such, pharmaceutical trade mark owners should carefully select and register their marks to minimize potential problems associated with including INNs or INN stems.

# Brexit, Digital, Slogans, Champagne and Biosimilars - a bouquet of Trade Mark and related matters.

## 94th PTMG Conference in Paris

Frédérique Potin, Simmons & Simmons LLP

13 March 2017, 2 p.m., the familiar hubbub of the PTMG conferences starts growing in the magnificent lobby of the Grand Hotel located between the Opera, the Galeries Lafayette and the Tuileries' gardens in Paris... a wonderful venue has once again been chosen for the pleasure and comfort of delegates.

Needless to say, the clear blue Parisian sky and generous sunshine added to the delight of the delegates at this year's Spring Conference.

When the familiar bell started ringing again to move into the Conference Ballroom of the Grand Hotel, we all held our breath on entering this extraordinary room surrounded by mirrors, statues, paintings and lights. It was time to kick-off the 94th PTMG Spring Conference.



As announced by Chairman Frank Meixner, the themes of the Conference were various, taking us from Comté cheese and Champagne to biosimilars, and from the French political situation to the questions raised

Frank Meixner

by Brexit, while having our usual round-up of international cases.

First we had the great honour of welcoming Mr Patrick Errard, Head of Astellas France and Chairman of the French association of pharmaceutical companies (the LEEM), who provided a detailed view of the current state of French pharmaceutical companies in light of the new challenges that are facing this industry, such as the increasing importance of the role played by patients in their treatment, the focus on personalized medicines and on the



Patrick Errard

provision of services accompanying the delivery of drugs, as well as the evolution (if not revolution) towards digital health. Mr Errard stressed that these new challenges required the adoption of a new business model for the pharmaceutical industry. The question is whether France is prepared for this evolution given its current economic context and political crisis, but when asked whether he would invest in France's pharmaceutical industry, the answer was a resounding 'Yes'.



Isabelle Leroux

are all waiting for is still some time off. As an illustration, Ms Leroux said a few words about the recent decision of the French Supreme Court (Cass civ, 25 January 2017 Sté H&M v Sté G-Star International) which held that a trainee, hired by a law firm acting on behalf of the plaintiff, cannot validly assist the bailiff in collecting evidence of the infringement.

It was then up to Nicola Dagg from Allen & Overy to inform us about the consequences of Brexit on trade marks. Several options are being discussed by practitioners in order to have EUTMs recognized in the UK after Brexit. Of course, each option has its advantages and drawbacks in terms of costs, burden of work and viability. Unsurprisingly, the PTMG audience voted largely in favour of the 'Montenegro' option under which all EUTMs should be automatically entered onto the UK Register (although the



Nicola Dagg

Register will run the risk of being cluttered by the large number of trade marks). In any event, right holders should include Brexit in their current projects, conduct Brexit risk assessments but not worry too much about any trade mark or regulatory cliff, as transitional work is underway.

It was then time for a tea break and socializing session for delegates, followed by a delicious dinner in the magnificent ballroom of the Grand Hotel. This dinner gave more than a taste of Emmanuel Baud's presentation of the next morning on designations of origin and geographical indications, with 'camembert de Normandie' and 'comté' cheeses, as well as wines served at dinner! After dinner some happy delegates also had the chance to discover the exciting Parisian night life in trendy bars of the capital!

The next morning, the first speaker of the day (after Chairman Frank Meixner's opening remarks), Benet Brandreth of 11 South Square, introduced us to the world of the digital market and its impact on



Benet Brandreth

trade marks. The 'Digital Single Market', or DSM, is a means of promoting access to digital goods and services through consumer protection cooperation, copyright Directive reform and the prevention of unjustified geo-blocking measures. In this respect, trade mark law is perceived as a block to the DSM, given consumers' wish to purchase goods or services cross-border without having to struggle with national laws and different branding based on territory!

A more traditional means of consuming goods was then presented to us by Emmanuel Baud from Jones Day, who took us on a guided tour of the protected designation of origins (PDO) and protected geographical indications (PGI) of France and elsewhere in the world. The difference between PDO and PGI may lead to some confusion: the 'aceto



**Emmanuel Baud**

balsamico tradizionale de Modena' is a PDO, with a 12 years ageing requirement in order to benefit from this PDO, while the 'aceto balsamico de Modena' is a PGI with no ageing requirement and with the

possibility to add caramel in the vinegar! In the wine industry, PGIs are very important to ensure success of a particular wine production. An interesting case can illustrate this principle: Chateau de Valandraud is a famous producer of wine benefiting from the Saint Emilion PGI. In 1999, following particular weather conditions in France, this producer covered his vineyard to protect it from watering. However, as this approach was not compliant with the conditions set out in the Saint Emilion PGI, the Château was not allowed to use its PGI for that year's production of wine. Chateau de Valandraud therefore decided to name its wine L'Interdit de Valandraud (Valandraud's Forbidden wine) but it was considered that the name Valandraud was so clearly associated with the Saint Emilion PGI, its use in the new sign could mislead consumers into believing that they were purchasing Saint Emilion wine...

Returning to more traditional topics for PTMG, Matias Noetinger from Noetinger & Armando made a very detailed and interesting presentation of pharmaceutical trade mark case-law and issues in Latin America. Throughout his tour, we learnt that, when seeking trade mark protection in Latin America, it is recommended to restrict the specification of goods as much as possible (to increase chances of registration), to negotiate co-existence agreements if at all possible (unless the trade marks are too close) and to review cases periodically as procedures may last for a long time.



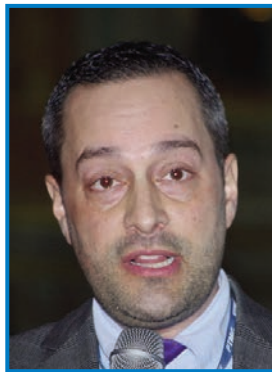
**Matias Noetinger**

Matias then handed over the floor to Bill Ladas of King & Wood Mallesons, from Australia, who presented the pros and cons attached to 'reputation' in Australia. Indeed, while reputation may result in an

extended scope of protection, for marks such as COCA-COLA or ADIDAS, it may for some other brands result in a lesser degree of protection: the famous chocolate treats

MALTESERS now have to co-exist with MALTITOS chocolates. The inconsistency of Australian decisions appears to result from a lack of guidance, a lack of structured approach and, also, a failure to look at EU case law. The appointment of a new and young Chief Justice specialized in comparative law may smarten up Australian case-law life!

It was time for lunch at the Grand Hotel which enchanted our taste buds with, in particular, a delicious mille-feuilles dessert...



**Timo Götting**

at this tricky time of the day! His first statement that today more than 2 billion people don't have access to medicines immediately caught our attention, as he moved on to talk about the necessity for biosimilars. A biosimilar is a regulatory term to designate an approved biological product which is highly similar to the reference product, and which has no clinically meaningful differences. Basically, the biosimilar offers the same safety and efficiency as the reference product. A hot topic for biosimilars is the issue of naming: the FDA has issued draft guidelines providing that biosimilar names must be composed of the nonproprietary name (NN) as core name + hyphen + suffix (e.g. infliximab-dyyb / adalimumab-atto). The suffix must be composed of 4 letters, of which 3 must be unique... These principles should be applied retroactively, although there is no implementation plan yet. Another stakeholder, Novartis, commented these draft guidelines, underlining in particular the fact that suffixes are not necessary. Novartis also



**Bill Ladas**

insisted on the high costs and burden of work that the new naming system would entail for stake holders, as well as the creation of a potential for confusion at all levels. Needless to say that harmonization between the FDA and EMA approaches is more than necessary!

The last, but certainly not the least, presentation of the day was made by Rosina Baxter of Reckitt Benckiser on the Protection of slogans for pharmaceutical products.



**Rosina Baxter**

Rosina took us on a tour of those memorable phrases used in all industries including the pharma industry to demonstrate that slogans are often part of the corporate identity even though use of slogans tends to be diminishing as different communication means with more limited place and time are being used. Nevertheless the EUIPO approach to the registration of slogans appears to be more favorable as shown in the European General Court decision of 29 January 2015 in which the Court asserted that the registration of marks used as slogans is not excluded by virtue of such use and that it is therefore inappropriate to apply stricter criteria to the registration of slogans. There are, however, countries in which slogans cannot be registered as trade marks (such as Brazil), while in other countries they must be registered with the brand (such as Chile). In these countries, it will therefore be advisable to keep records regarding the creation of slogans in order to be able to establish ownership and date of creation, when claiming copyright protection. As of today, slogans used in the pharma industry must also comply with advertising and pharma regulations, as well as with professional codes of conduct. For instance, the term FAST may only be used in relation with a drug having effect in less than 30 minutes, whereas IMMEDIATE or INSTANT may be used if effect is in less than 10 seconds.

It was on this very interesting topic that the Chairman closed the conference, underlining once again the incredible quality of the presentations and speakers. Delegates were invited to our next rendez-vous in two new exciting destinations: Toronto for the Autumn conference and Porto for the 2018 Spring conference. It was then time for delegates to say their goodbyes and enjoy the rest of the day in sunny Paris!

# Parallel Import in the Single Market – brand owner rights confirmed

Rachel Cockburn, Ferring Pharmaceuticals and Thomas Ryhl, Njord Law Firm

It is well-known that pharmaceuticals are a particularly good target for parallel trade in the European Union given the range of pricing and re-imburement policies across the 28 member states. For over twenty years, European law has struggled with the tension between the rights of brand owners under the Trade Mark Directive and the rights of parallel importers to move goods freely across borders under the Treaty of Rome. For over 20 years, almost unanimous jurisprudence has found the middle-ground with the 'BMS' conditions.

Much of the legal debate around these requirements has dealt with 'necessity'. The BMS judgment stated that: '... , save in the circumstances defined in Article 7(2), Article 7(1) of the directive precludes the owner of a trade mark from relying on his rights as owner to prevent an importer from marketing a product which was put on the market in another Member State by the owner or with his consent, even if that importer repackaged the product and re-affixed the trade mark to it without the owner's authorization.' [Para 37]

But also that: 'The power of the owner of trade mark rights protected in a Member State to oppose the marketing of repackaged products under the trade mark should be limited only in so far as the repackaging undertaken by the importer is necessary in order to market the product in the Member State of importation.' [Para 56]

Thus, the legality of re-packaged branded parallel importation rests on an exception to the rule, to be applied only in cases where such re-packaging is necessary. Put differently, brand owners should only be prevented from exercising their exclusive right against parallel importers' use of their trade mark when they deliberately create an artificial partitioning of the single market by, for example, using different brand names or selling different pack sizes in the member states.

In 2012, Orifarm notified Ferring that it intended to import Ferring's KLYX® (sodium ducosate) product into Denmark from Norway. Orifarm planned to buy

10-piece packs in Norway, re-package them to 1-piece packs and sell them in Denmark under Ferring's trade mark. Given that KLYX is marketed throughout Scandinavia in both 10-piece and 1-piece packs, Ferring notified Orifarm that it objected to the proposed re-packaging within the standard 15 working days of notification. Orifarm nevertheless continued as planned. Ferring was compelled to assert its rights and sued Orifarm for infringement of its KLYX trademark [Case V-12-13, Ferring v Orifarm, Sø- og Handelsretten]. Ferring argued that such assertion of trade mark rights is permitted as it would not artificially partition the market: Orifarm was not obliged to re-pack the 10-pack bought in Norway into 1-packs in order to sell the product in Denmark. Orifarm could have bought single packs in Norway or, if it preferred to buy 10-packs, then it could equally re-sell those in Denmark. Re-packaging was not necessary.

KLYX is, by no one's standards, a block-buster but Ferring's action was about principle not profit. Orifarm had not established that the exception to the fundamentals of trade mark law should be applied to its marketing and sale of KLYX in Denmark. Not only had Orifarm not respected Ferring's right to object to the proposed re-packaging by refraining from marketing in the face of the trade mark owner's objection, but Orifarm's re-packaging was not necessary in order to gain access to the market and was purely for commercial advantage. Orifarm's stance was that Ferring's attempt to hinder its parallel import of KLYX was illegal, and that no justification for repackaging is necessary or, if it is, that the re-packaging was required to gain access to a portion of the Danish market, being the 1-pack sub-market. Not long after, Orifarm also notified Ferring that it intended to repackage (not just re-label) 10-packs purchased in Norway to be sold as 10-packs in Denmark, again using the Ferring KLYX trademark.

Before its case came to trial, however, Ferring's commitment to principle was tested. On 9 October 2013, the German Supreme Court decided a parallel import

matter between Boehringer Ingelheim and Eurim-Pharm. The facts were that SIFROL® was sold in packages of 30 and 100 tablets in both Germany and France. Prescription practice made 30 tablets the most popular size in France (80% of sales), but not in Germany. Eurim-Pharma purchased 30-packs in France and repackaged to 100-packs for sale in Germany, being the preferred pack size in that market. Boehringer opposed, claiming such re-packaging was not necessary, as the 100-packs were also sold in France and there was, therefore, no artificial partitioning of the markets. The German Supreme Court decided in favour of Eurim stating that 'the jurisprudence is clear as to the fact that an exclusion of a parallel importer from a part of the market could constitute an artificial partitioning of the market.'

Ferring was, therefore, faced with a strong precedent for the Danish court to support Orifarm's position. Furthermore, and more importantly, Ferring and the pharma industry at large was faced with a deviation from European trade mark jurisprudence delicately balancing the rights of brand owners with the free movement of goods in the single market. Would this mean that almost any kind of repackaging is now allowed, even when solely for economic reasons? Once more, Ferring felt compelled to act: not only to protect its consumers and its integrity but to protect legal principle. Ferring requested, and the Danish Court agreed, a preliminary ruling from the CJEU. The question being whether a trade mark owner can oppose the parallel import of trade-marked pharmaceutical products, whose package has been modified by the importer when both 10-piece and 1-piece packs were available in both the country of export and the country of (parallel) import.

Interestingly, both Ferring and Orifarm relied on the same statements from the BMS case in support of their claims but Ferring remained firm in its belief that, while the Germans courts may have forgotten about the original reasoning of the CJEU in parallel import cases, the CJEU had not and that para.s 54 to 56 of Justice Gulmann's decision were aimed at

*continued on next page*



prohibiting exactly what Orifarm was doing with KLYX in Denmark (and what Eurim-Pharm had done with SIFROL in Germany).

Two years later, Ferring was proven right. The CJEU indeed re-stated the legal principle in Ferring's favour, as well as in the favour of all other original manufacturer brand owners.

Ferring/Orifarm (judgment of 10 November 2016, Case C-297/15, Ferring Lægemidler AS v Orifarm AS):

'[...] the change brought about by any repackaging of a trade-marked medicinal product — creating by its very nature the risk of interference with the original condition of the product — may be prohibited by the trade mark proprietor unless the repackaging is necessary in order to enable the marketing of the products imported in parallel and the legitimate interests of the proprietor are also safeguarded.' (para.19), concluding that

'[...] a trade mark proprietor may object to the continued marketing of a medicinal product by a parallel importer, where that importer has repackaged that medicinal product in a new, outer packaging and reattached the trade mark, where, first, the medicinal product at issue can be marketed in the importing State party to the EEA Agreement in the same packaging as that in which it is marketed in the exporting State party to the EEA Agreement and, second, the importer has not demonstrated that the imported product can only be marketed in a limited part of the importing State's market, and those are matters which it is for the referring court to determine.' (para.29).

Ferring, and the pharmaceutical industry, has not been able to enjoy the Danish court's application of principle to the facts as Orifarm has surrendered its case pre-trial. Nevertheless, this truly has been a victory of principle over profit, and a long needed reminder that the principles stated in BMS still prevail, with branded re-packaging being a rare and narrowly limited exception to the general rule of the brand owner's exclusive right to use the trade marks, despite the many attempts by parallel importers to challenge these principles at the expense of owners' rights.

Ferring was represented before the Danish Court and the Court of Justice of the European Union by Thomas Ryhl of Njord Law Firm.

## Above the curve

Yvonne Onomor, Olswang

The General Court overturned the decisions of both the EUIPO and Board of Appeal allowing Novartis AG to register its curve trade marks.

### Facts

Novartis filed the below two figurative marks for pharmaceutical preparations in class 5.



The examiner refused the applications for lack of distinctiveness claiming the marks were (i) reminiscent of the shape of the goods covered and (ii) too simple to be distinctive. Novartis' appeals against the examiner's decisions were similarly rejected.

The Fifth Board of Appeal (Board) sided with the examiner and held that:

- the marks would be perceived as representing the stylised outline of an oval shaped pharmaceutical lozenge or pill even though they were not a faithful representation of such goods;
- the marks were not 'merely' too simple. 'Rather,' they consisted of a series of components, which did not allow the consumer to differentiate the pharmaceutical preparations of other manufacturers;
- as pharmaceutical preparations are commonly marketed in the form of pills, tablets and lozenges which are often round or oval in shape, the applied for 2-dimensional figurative marks did not depart significantly from the norms or customs of the sector to be distinctive.

On appeal to the General Court, Novartis argued that the Board was wrong to conclude that the marks resembled 'pills.' Being abstract and ambiguous, the signs could be interpreted in several ways, and their unique character made them recognisable by the concave impression created by the different shades of green or grey. The shape more closely represented the letter 'C,' and not a full circle, and did not resemble the shape of a pill. As such, the consumer would perceive the signs as a crescent shape and the different shading of grey or green created either an abstract image of an eclipse; a representation of the letter 'C'; or an elegant or unusual design.

### Decision

Accepting Novartis' arguments, the Court held that, as with 3D marks consisting of the appearance of the goods themselves, 2D figurative marks consisting of the representation of the goods for which registration is sought, must depart significantly from the norms and customs of the sector to be registered. However, this needed to be weighed-up against the established principle that a sign need only possess a minimal level of distinctiveness to be registered.

The Court stated that the Board's assessment of the signs as being reminiscent of the shape of a pill, tablet or lozenge in relation to the class 5 goods was therefore incorrect. The signs more closely represented the letter 'C' or a crescent and it was very unlikely that the relevant public would perceive the signs as a shape of a pill even when affixed to the pharmaceutical packaging. The slight twist in the signs and a play of light and shadow steers the relevant consumer even further away from the representation of a pill.

The examiner's second finding that the mark was 'too simple' to be distinctive, was also rejected. The Court recognised that an excessively simple sign that consists of a basic geometrical figure, such as a circle, a line, a rectangle or a conventional pentagon, is not, in itself, capable of conveying a message which consumers will be able to remember, and will not regard it as a trade mark. However, the crescent shape or the letter 'C' depicted in Novartis' signs was not a geometric shape. The different shades of colour and the curves of varying thickness with a slight twist were characteristics that distinguished the signs in the eyes of the public and which altogether endowed the signs with the minimum distinctive character necessary for registration.

### Comment

The Court appears to reject the notion of looking at the overall impression created by the signs on the relevant consumer in favour of an analytical assessment of the signs' component parts. Given the Courts reasoning, and the importance placed on the shading of colour and 'twist' of light created by the signs, it is doubtful whether the Court would have taken a different standpoint if the signs took the form of a complete circle.

Novartis AG v European Union Intellectual Property Office (EUIPO) joined cases T-678/15 and T-679/15 (judgment of 15 December 2016)

# Italy – Justified non-use, enhanced consistency

Laura Pedemonte, Barzanò & Zanardo

## Facts

In 2001, the Italian pharmaceutical companies OP Pharma S.r.l. (hereinafter, for short, OP) and Società Prodotti Antibiotici S.p.A. (hereinafter, for short, SPA) signed a distribution agreement and a subsequent related letter of intent, whereby OP granted SPA the right to market a medicinal product for the local treatment of pain and inflammation of joints, muscles, tendons and ligaments for a period of three years, automatically extendable under certain circumstances.

According to the agreement, OP was the Marketing Authorization Holder (MAH), whereas SPA acquired the right and the obligation to handle scientific information, advertising, sales of the product and the right to register its related trade mark TOPFANS in Italy.

In 2005, OP ceased to supply SPA with the relevant drugs and the latter directly and indirectly sold out the products under the TOPFANS mark until September 2008.

In March 2008, the parties started a lawsuit on the ownership of the above mentioned trade mark, which ended in October 2011 with a final Court judgement in favour of SPA.

In June 2013, OP filed a cancellation action based on non-use against SPA before the Court of Milan alleging that SPA had not used its TOFANS mark during the previous five years.

## Brief overview of non-use cancellation actions in Italy:

In Italy, cancellation actions based on non-use are Court proceedings to be instigated before the competent Court based on the ordinary rules of civil procedure. The burden of proof of non-use lies with the claimant. This burden has to be *prima facie* satisfied with positive evidence such as surveys, submission of relevant trade magazines and/or investigation reports demonstrating non-use of the challenged sign. In order to avoid cancellation, the defendant has to prove that the mark has been used in the last five years by himself or with his consent (e.g. use by a licensee), save where the failure to use it can be justified by a legitimate reason.

## Decision

The Court rejected the cancellation action, deeming that SPA had proved an effective use until September 2008 and a subsequent justified non-use until September 2013.

As far as the period from March 2008 to October 2011 was concerned, the Court found for legitimate non-use of the mark. According to Italian case law, the proceedings on the ownership of a mark, not predictable at the time of its filing, have to be considered as a justified non-use, based on the fact that it is an incontestable business decision aimed to avoid unfavourable rulings on damages.

Furthermore, the Court also acknowledged a legitimate impediment for the period from September 2008 to September 2013 due to Government requirements such as official directives and guidelines. The Court found in this context, without giving specific reasons, that even though EMA's Guideline on the acceptability of names for human medicinal products processed through the centralized procedures (in its version of 22 May, 2014) deals only with trade marks in the context of the centralized EU-wide authorization procedure for pharmaceutical products, it applies directly to this case.

Article 4.1.1. of the above Guideline provides that, in principle, a five-year period must have elapsed from the official invalidity of the marketing authorization, before being allowed to use the same (invented) name (i.e. trade mark) for other medicinal products.

Actually the centralized authorization procedure [Regulation (EC) No 726/2004, art. 6] provides that each marketing authorization request may relate to one name only. Therefore, having terminated the agreement with OP as well as the marketing of the product under the TOPFANS mark (of which OP was the MAH), SPA could not use the mark for other pharmaceutical products before the period established according to regulatory procedures had elapsed, so that the public would forget the association of the mark with the previous drug, in order to avoid a serious risk of confusion.

Once the MA is granted, according to Commission Regulation (EC) 1234/2008, the name of a medicinal product may be modified only if the same MA is changed by its holder through a special procedure.

Considering this strict link between MA and the trade mark of the drug, the Court of Milan deemed as a justified non-use the circumstance that, between the end of the marketing period of TOPFANS and the proposition of the non-use revocation action, the five-year period had not elapsed, and therefore the trade mark could not be used for other medicinal products.

## Comments

The decision is relevant for the following aspects:

(1) As to proper reasons for non-use, it confirms Italian case law, deeming that pending invalidation action against the trade mark exempts the trade mark owner from the obligation to use this trade mark in the course of trade. It is worth highlighting that this case law is not consistent with the EUIPO jurisprudence, according to which, in general, a pending cancellation action against a mark should not exempt its owner from the obligation to use the trade mark in the course of trade: 'It is for the proprietor of a trade mark to conduct an adequate assessment of its chances of prevailing in the revocation proceedings and to draw the appropriate conclusions from that assessment as to whether to continue to use its mark' (T-250/13, SMART WATER, § 73). In the same sense, R 0764/2009-4, HUGO BOSS, § 19.

(2) However beyond such reasoning, applicable in a general way to any other category of goods, the decision of the Court of Milan points out the relevance of other specific legitimate reasons for non-use of the mark in question, attributable to the pharmaceutical industry, which deserve to be highlighted. In particular, the Court stated that the five-year period from the end of the marketing period of the medicinal product, before being allowed to use the same trade mark for other medicinal products (provided by the a.m. article 4.1.1. of the Guideline) shall be considered as a proper non-use of the mark. As a matter of fact, the MA involves not only the medicinal product but also its trade mark.

(3) Last but not least, it is worth observing that the Court held the aforementioned EMA Guideline directly applicable to the Italian national health authorization procedure, despite the three-year period provided for by art. 38.5 of the Italian D.Lgs No. 219/2006 (implementing the Directive 2001/83 on the Community code relating to medicinal products for human use), after which the MA expires in case of non-use of the product on the Italian market.

The judgement of the Court remains silent on why it decided to refer directly to Art. 4.1.1. of the EMA Guideline. We may assume as a matter of precaution and to maintain consistency between European and national legislation in this field.

# Long Awaited IP Code of Turkey

Güldeniz Doğan Alkan, Gün + Partners

In the 1990s, Turkey swiftly prepared and published decree-laws related to IP rights in order to fulfill its obligation of adopting national legislation related to IP rights with EU regulations so to become a member of the Customs Union. Decree-Laws which have the power of law were preferred since the procedure for passing them is less cumbersome and faster. They should have been converted into laws following the membership of Turkey to the Customs Union; however they remained as decree-laws until the publication of the IP Code No. 6769 on 10 January 2017.

Decree-laws have a contradictory nature in Turkish Constitutional Law. Indeed, the Constitutional Court annulled a few provisions of the IP decree-laws based on Article 91 of the Constitution which states that property rights cannot be regulated by decree-laws and instead they should be regulated by codes. The last annulled provision was Article 14 of the Decree-Law No. 556 relating to revocation of non-used trade marks and the annulment decision was published in the Official Gazette just a few days before the publication of the IP Code. The Parliament preferred for the last few years to integrate annulled provisions into the present decree-laws and therefore, there was an intense need for a comprehensive IP Code.

According to the general preamble of the IP Code, it is prepared to adopt recent developments in EU IP law, abstain from the annulment decisions of the Constitutional Court and render the relevant regulations clearer, more understandable and systematic.

The IP Code unites all IP rights, i.e., trade marks, patents, industrial designs, utility models, geographical indications and traditional product names. The code consists of five chapters, 193 articles and 6 provisional articles. Most of the provisions in the IP decree-laws were inserted into the code and revisions were made in line with the Draft Law no. 1/756 which however failed to pass in Parliament and therefore became obsolete in 2013. Book 1 of the IP Code regulates trade marks, Book 2 regulates geographical indications and traditional product names, Book 3 regulates designs, Book 4 regulates patents and utility models and Book 5 regulates common provisions. Article 188 changes the name of the Turkish Patent Institute to Turkish Patent and Trademark Office (TPTO).

When we look at the novelties brought by the IP Code, we see at first that the IP Code uses the term 'industrial property' and in Article 2-(i), 'industrial property right' is defined as 'Trade mark, geographical indication, industrial design, patent and utility model.' Indeed, even the name of the Code is the 'Industrial Property Code'.

Even though the IP Code repealed the IP related decree-laws, provisions of the repealed decree-laws will be implemented for the pending trade mark and design applications filed before the IP Code entered into force according to Provisional Article 1.

The IP Code introduces the 'co-existence principle' for trade marks. According to Article 5-(3) of the IP Code, the TPTO cannot ex-officio refuse a trade mark application on the grounds that it is identical with or indistinguishably similar to a trade mark registered or previously applied for registration for the same or same kind of goods/services, if a notarized letter of consent from the senior trade mark owner to the registration of the application is submitted to the TPTO. This is important to overcome the present ex officio refusal authority of the TPTO under Article 7/1(b) of the Decree-Law No. 556 which blocked registration of many trade mark applications.

According to Article 26, the TPTO has the right to revoke a trade mark on the grounds that (1) if, within a period of five years following publication of registration, a trade mark has not been put to use without justifiable reason for the registered goods or services, or its use has been suspended for an uninterrupted period of five years; (2) if, a trade mark becomes a generic name for the goods and services within its scope, due to the acts of the trade mark owner; (3) if, as a result of the use made by the trade mark owner or the person authorized by him, there exists likelihood of confusion on the part of the public as to the nature, quality and geographical origin of the goods and services within its scope. However, this provision will only enter into force seven years hence and until then the right to revoke a trade mark in line with the above three situations will belong to the competent IP Courts.

According to Article 19-(2), during the opposition proceedings, the TPTO will demand evidence from the opponent to show genuine use of its trade mark in Turkey which constitutes grounds for opposition for the five years prior to the application date of the opposed application or justified reasons for non-use, on condition that the applicant of the opposed trade mark application requests so and the trade mark upon which the opposition is based has been registered in Turkey at least five years before the application date of the opposed application. If the opponent cannot prove genuine use of its trade mark, the opposition will be refused. If the opponent proves genuine use of its trade mark only for some of the goods/services within its scope, the opposition will be examined only based on these goods and services. This 'counter non-use claim' can also be used as a defense in infringement and invalidation actions.

There was no clear provision for the time frame of 'loss of right by remaining silent' principle in the Decree-Law No. 556. The Court of Appeal accepts that the right holder can lose his rights by remaining silent for a long time, even if the counter party is in bad faith. It is stated in the Turkish doctrine that the time frame must be determined by taking into consideration the conditions of tangible case and pursuant to the 'Principle of Honesty'. Article 25-(6) states that 'In case a trade mark owner has remained silent for the five consecutive years where he knows or should know that the later dated trade mark is used, he cannot allege its trade mark as an invalidation ground unless the subject trade mark registration was filed in bad faith.' Therefore, a 5 years period is clearly accepted as the time frame for 'loss of right by remaining silent' principle.

Article 163 brings 'fast destruction procedure'. Accordingly, in case the seized counterfeit products are subject to damage, to substantial loss of their value or their preservation constitutes a serious burden, following the expert examination, the Court can decide their destruction upon the request of the prosecutor before a final decision on the merits of the case is rendered.

The other new provisions within the IP Code relating to trade marks are as follows:

- Article 4 brings a new condition for signs to be registered as trade marks which is: 'can be shown in the Registry ensuring that the subject of the protection provided to the trade mark owner is clearly and explicitly understandable' and changes the terminology from 'all kinds of signs being represented graphically such as words, including personal names, figures, letters, numbers, shape of the goods or the packaging thereof' and 'similarly descriptive means capable of being published and reproduced by printing' to 'all kinds of signs such as words, including personal names, designs, colors, letters, numerals, sounds and shape of the goods or their packaging,' so as to be in line with the terminology given in Article 3 of the Directive (EU) 2015/2436 of the European Parliament.
- Signs which contain registered geographical indications cannot be registered as trade marks as per Article 5-(i).
- Bad faith filing is regulated as a separate ground for opposition and invalidation in Articles 6-(9) and 25-(1).
- Timeframe for filing an opposition

*continued on next page*

against an application has been shortened from three to two months with Article 18.

- According to Article 6-(4), trade mark applications identical to or similar with well-known trade marks in the context of Article 6bis of the Paris Convention will be rejected upon opposition in respect of the same or similar goods or services. This is also regulated as a ground for invalidation. This article is important since the protection of well-known trade marks in the context of Article 6bis of the Paris Convention in the Decree-Law No. 556 was cancelled by the Turkish Constitutional Court in 2015.
- According to Article 7-(5) (c), a trade mark owner cannot prevent third parties from using its trade mark on accessories, spare parts or equivalent parts, where it is necessary to specify the purpose of use of the goods or services, provided that such use is compliant with the principles of good faith and commercial life. The terminology for exceptions to the scope of the rights arising from a trade mark registration was changed to be compatible with the terminology of Article 14 of the EU Directive No. 2015/2436.
- The IP Code adopted the principle of international exhaustion unlike the Decree-Law No. 556 which accepted national exhaustion principle of IP rights. According to Article 152, acts related with the products subject to protection of industrial property rights shall fall outside the scope of the rights, where such acts occurred after those goods had been released into the market by the right owner or with his consent. Consequently, exhaustion of IP rights has been limited to the products released to the market and does not apply to next-generation products before they have been released.
- Lastly, contrary to the precedents of the Court of Appeal, having a registration will not automatically mean that there is no infringement, since according to Article 155, the owner of a trade mark, patent or design right, cannot assert its registered IP right as a defense in an infringement action filed by a priority right owner.

Turkey is a rising star among the global economies and well-protected IP rights is one of the keystones to having a strong economy. The IP Code brings complete or partial solutions to some of the main problems of the Turkish trade mark law and we will observe the practical impacts of the IP Code following the adoption of the implementing regulations by the TPTO and implementation of the Code by the TPTO and the Courts.

## Medicinal cannabis lays down roots in Australia

Jackie O'Brien (partner) and Lauren Holz (Graduate), Norton Rose Fulbright

It looks like growth season for Australian medicinal cannabis. Not only were the first private licences for medicinal cannabis issued this year, but in February the Federal Government also announced a plan to temporarily loosen importation controls to boost Australia's supply until local growers can catch up to demand.

The market, meanwhile, has reacted quickly: two high performers from recent IPO listings have ties to medicinal cannabis and various international companies announced their intention to apply for Australian licences. But this rare new space in our crowded pharmaceutical market comes with its own range of regulatory and IP challenges.

### Prescriptions

Medicinal cannabis is not approved by Australia's Therapeutic Goods Administration (TGA), so only doctors who are authorised providers or who obtain medicinal cannabis on a patient-by-patient basis through an access scheme can prescribe it.

Both avenues require multiple stages of review by the TGA, and approval is also subject to the laws of the states and territories, some of which restrict access far more heavily than others.

### Local cultivation and manufacture

Companies looking to enter the Australian market should monitor local demand for, and access to, medicinal cannabis, because Australian-grown cannabis cannot yet be exported. Interested parties can apply for a medicinal cannabis licence – covering cultivation, production or both – from the Office of Drug Control (ODC). The application process requires a good deal of forward planning. For example, applicants are required to provide very specific proposed operational details, including security measures, detailed site and floor plans, and evidence that product would only flow on to other licence-holders. Mixed-use cultivation is not allowed, so medicinal cannabis must be kept strictly separate from any industrial hemp crop.

An equally stringent licence is also required for the manufacture of narcotic drugs involving cannabis. This is in addition to a requirement that manufacturers hold a Good Manufacturing Practice licence from the TGA and comply with any licensing requirements imposed by the state or territory in which the manufacturing site is located.

Applicants for cannabis-related licences are also subject to a fit and proper person test, which extends not only to the applicants themselves, but also to anyone who could substantially influence the conduct of activities under a licence. This list potentially includes business associates and family members. Corporate applicants can expect a wide-ranging review of the body corporate's directors, officers, shareholders and staff, plus the body

corporate itself, on issues including criminal history, potentially risky associations, regulatory compliance, business experience and financial history.

### Importation

Importation of medicinal cannabis is usually on a per patient basis and only after the prescription has been approved. Importers require both a licence (valid for 12 months) and a permit (for each importation) to proceed with shipment. However, in February the Federal Government agreed to process import applications ahead of prescription approvals. This is a temporary measure intended to reduce waiting periods before the Australian product hits the market. Before lodging those bulk orders though, there are a few things to keep in mind. Importers are required to comply with the conditions applied to drug imports under the Customs (Prohibited Imports) Regulation 1956 (a serious undertaking in itself), as well as some specific conditions set out in the Therapeutic Goods Regulations 1990. These include requirements that the supply be securely stored and any unused material destroyed after 12 months. The TGA also imposes quality control standards for cannabis products, including imported products, through the Therapeutic Goods Order No. 93.

### Protect your plants

Although current advertising restrictions may somewhat inhibit brand recognition as the industry develops, companies looking to enter the medicinal cannabis market should think proactively when it comes to IP. Several pharmaceutical companies have already lodged Australian patent applications in respect of medicinal cannabis products, including for a medicinal edible. Companies should also think strategically about trade marks while the Australian register remains relatively clear of cannabis-related marks. The stringent licensing requirements are likely to limit the competitive field for the time being, but these may not last forever. As well as helping to stake out a brand identity during the crucial early stages of the Australian medicinal cannabis industry, a well-planned set of trade mark registrations would assist in preserving that identity in the event of deregulation. As with all prescription medications, companies should plan for the possibility that medicinal cannabis could migrate to the over-the-counter market, for example by conducting comprehensive clearance searches to ensure proposed branding will not infringe existing marks in the OTC space.

IP protection in Australia should, hopefully, prove more straightforward than in the US, where the illegality of cannabis under federal law restricts trade mark registration opportunities. It will be worth observing how our first generation of licensees establish their IP portfolios as their products approach market-readiness.

# PROFILE: Tapio Blanc

Tapio Blanc is Head of the Global Trade Marks Function of F. Hoffmann-La Roche AG in Basel, Switzerland, since 2016. He is a Swiss Lawyer graduated from the University of Basel. Before joining Roche, he worked in a law firm, at the Courts and in the Administration of Basel-City.

Tapio is a PTMG Committee Member, MARQUES Council and Team Member, INTA and ECTA Member. He is also in the trademark committees of efpia, Vfa and a member of the Expert Group Intellectual Property at Economiesuisse.

He is fluent in German, English, French, Italian and Finnish.



## **Where were you brought up and educated?**

I was brought up by my parents in Basel by a traditional upbringing and family life and I studied law at the University of Basel.

## **How did you become involved in trade marks?**

By purpose! As a child I always put a ® or ™ symbol above my name. On drawings or stories I had to do in school I put a © symbol on it. As I was a songwriter for more than twenty years, I registered them with the Swiss Copyright Society and I was aware of IP from a very early stage on. Trademarks always had a mystical fascination to me. It was just always there.

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

Popstar in London (2) Formula 1 driver (3) Striker for Manchester United or Liverpool (4) Politician (5) Criminal Lawyer (6) Strict History Teacher.

## **Which three words would you use to describe yourself?**

The three P's: Power, Pace and Passion!

## **Complete the following sentence.**

**"I wish ...."**

I had a time machine!

## **What's the best thing about your job?**

I appreciate working for Roche as I was always given trust and the possibility of scope for design in my field. I have very qualified and loyal colleagues in my department, I love trademark management and the leadership of people. Maybe the

most I enjoy meeting so many interesting and unique trademark personalities from all over the world!

## **What does all your money get spent on?**

Travel, travel and travel.

## **What do you wish more people would take notice of?**

The achievements and importance of the pharmaceutical industry for mankind. All the wars together in the last 2500 years have produced 455 million deaths. Compared to that only three anti-infectives of Roche (Rocephin®, Bactrim®, Rimifon®) have saved many billion humans!

## **What is your philosophy in a nutshell?**

Being authentic and follow counter-cyclical behaviour in a supersonic way.

## **Who was your mentor or role model?**

For trademarks my now retired boss Dr. Hans-Friedrich Czekay.

## **What car do you drive?**

Jaguar F-Type, British Racing Green.

## **Whom do you most admire and why?**

The Queen for serving her country since 1952 with an unseen sense of duty, discipline and belief.

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

"Weirdo" of The Charlatans (1992).

## **What is your all-time favourite film?**

Alfred Hitchcock's Psycho (1960), Rear

Window (1954) and Frenzy (1972), Casablanca (1942), Woody Allen's Matchpoint (2005), Mad Men (2007 – 2015), House of Cards (1990 UK), Quadrophenia (1979) and all James Bond (1962 – today)

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

Margaret Thatcher.

## **What is your favourite restaurant?**

San Francisco: John's Grill, London: Simpson's, Budapest: Gundel, Paris: Chez Maxim's, Dallas: Del Frisco's.

## **What is your favourite drink?**

Champagne.

## **Which word or sentence do you most often say?**

"Absolut!"

## **What is your favourite holiday destination?**

United Kingdom, San Francisco, New York, Copenhagen, Paris and Iceland.

## **What is your favourite item of clothing?**

A golden tie pin I got as a present .

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

When you come in summer put your best bath trousers on and swim with me down Basel in the river Rhine!

## **What do you like, even it's not fashionable?**

Oh, so many things! Carpets, exotic paperhangings and to address people by surname.

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