Law Lore & Practice

Pharmaceutical Trade Marks Group

Sept 2014



Editorial: Belgium, Scotland . . .

A little known holiday destination, De Haan, a town on the coast east of Ostende has earned itself the tagline "the Saint Tropez of Belgium". Certainly, the size of the holiday villas and the price of the waffles tend in that direction! An annual small town festival in early August celebrates life in the 1900's and whisks you back to a world often erased from our collective memory by

the coming of the first of the 20th century hostilities. Of course, this year, the drive from the beach to the French port town of Calais was decorated with sombre memorabilia of the centenary we are now remembering on a daily basis.

Belgium was of course invaded militarily twice in the last one hundred years and some would say that an ever growing mass of European civil servants are constantly invading today. Too often reduced to its role in today's geo-political strategies, Belgium continues to astound as it functions without a formal national government. More surprisingly, in more recluse parts of that country, away from the hub of the European crossroads, bilingualism is barely celebrated, often hidden. Indeed linguistic differences make shopping for your beach necessities in French a

challenge as shopkeepers pride themselves in only communicating in Flemish.

As trade mark practitioners, we are often guilty of reducing this country to its capital, Bruxelles; the Commission and the Parliament, Directives and Regulations and the impact thereof upon our daily lives. The creation of the economic area known as the Benelux in 1958 was one step towards federalising Europe which, from an administrative point of view, was applauded as simplication. However, in the past 25 years, our continent has moved towards more break up rather than regrouping and this month the Scottish people may decide to take another step along their path towards independence. My heart goes out to trade mark administrators who may find themselves facing yet another round of re-instatements, this time of former United Kingdom rights.

Looking ahead, swimming in another part of the North Sea might become a highly fashionable and exotic holiday desintation of the 21st century.... Whatever the outcome of the Scottish referendum, it will provide plenty of discussion at our upcoming conference. Bon voyage!

Vanessa

Healthcare advertising in Germany: no longer a lottery?

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

Under German law, pharmaceutical companies are not allowed to advertise pharmaceuticals to consumers when such is coupled with lotteries, competitions or other such games of chance insofar as such advertising abets inappropriate or excessive use of pharmaceuticals.

Different rules apply if the games of chance are exclusively addressed to healthcare professionals. Such advertisements are not per se prohibited. The claimed winnings are, however, time and again classified as unlawful advertising gifts or benefits within the meaning of § 7 HWG (German Drug Advertising Act). Under said section, gifts and other benefits for drug advertising purposes are broadly prohibited with the exception of low-value winnings such as simple plastic pens or note pads.

In its high-profile "Testen Sie Ihr Fachwissen" decision dated 12 December 2013, the German Federal High Court of Justice clearly limited the advertising restrictions under § 7 HWG and defined new criteria for the evaluation of advertisements with games of chance addressed to healthcare professionals.

The German Federal High Court of Justice dismissed the complaint. The court ruled that unlawful advertising exists only if gifts or other benefits are offered, announced, or granted which substantiate, the possible risk that the target groups of the advertisements shall be unobjectively influenced. According to the court, § 7 HWG is (only) supposed to prevent sales promotional practices capable of causing financial interest for healthcare professionals to prescribe or give away the advertised pharmaceuticals. In the case litigated however, it was not evident to the court that the winning chances could influence healthcare professionals to

change their customer consulting practices in some way beneficial for the promoted analgesic and for reasons other than the merits of the product advertised.

Comment

Advertisements are designed to influence. However, not every advertisement with lotteries, competitions, and the like determined by chance and addressed to healthcare professionals is unlawful just because the winnings offered are attractive and have some value. The decisive question in each case is rather whether a risk exists that the target groups of the advertisements will be unobjectively influenced. Applying the principles established by the German Federal High Court of Justice, one shall in the future be able to generally assume such risk only if the advertisement is capable of causing an individual financial interest in prescribing and/or giving away pharmaceuticals. The thankfully clear words of the German Federal High Court of Justice shall in the future provide pharmaceutical companies with considerably more leeway in how they design games of chance for doctors and other healthcare professionals in Germany.

Words from the Chair



The summer (in Europe anyway) is drawing to a close already and I hope many of you have been able to enjoy some lovely holidays over the last few weeks.

I was fortunate to spend a few weeks in the US with my family and saw some fantastic places.

It seems only very recently that many of us gathered in London for the Spring Conference and when you are reading this, it will almost be time for the Autumn Conference. Registration for the Conference was filled very quickly which I think is testament to the great reputation PTMG has for organising interesting and topical meetings (as well as picking fabulous venues and arranging good social events!).

The programme is now in place and we have a great team of speakers lined up to speak on some very interesting subjects.

I am looking forward to seeing many of you in Chicago very soon. I hope the weather is kind to us; as you probably know, Chicago is known as the "windy city"!

Safe travels and see you soon.

Sophie Bodet

Femivia and Femibion confirmed confusingly similar

Robert Guthrie and Roberto Pescador, London office of King & Wood Mallesons SJ Berwin

In its decision of 16 July 2014, the General Court has upheld an opposition to register as a Community Trade Mark (CTM) the mark FEMIVIA in relation to products for the treatment of medical conditions related to the menopause in class 5 on the basis of an earlier figurative mark for FEMIBION (which covered identical goods).

The Opposition Division had initially refused the opposition on the grounds that 'fem' had a weak distinctive character for the relevant goods. However, the Board of Appeal found there was a likelihood of confusion from the viewpoint of the Spanish-speaking sector of the relevant public (made up of both the general public and medical professionals). This reliance on the Spanish-speaking public was at the heart of the trade mark applicant's appeal to the General Court.

In relation to commonly used prefixes, the General Court's decision confirmed that they have a weak distinctive character and might be understood by the relevant public as descriptive of the goods covered by a mark. However, it could not be ruled out that such elements hold an autonomous position in the overall impression conveyed by a mark and, therefore, they had to be taken into account when comparing the signs in issue.

Decision

The General Court confirmed that, in assessing the likelihood of confusion between CTM marks, it is necessary to take into account the perception of the marks at issue by the consumer of the goods in question across the whole European Union. However, it was sufficient if a likelihood of confusion existed in only part of the European Union. Accordingly, the Board of Appeal was able to find likelihood of confusion between the marks on the part of the relevant Spanish-speaking public and did not need to assess whether the likelihood of confusion existed in relation to other parts of the relevant public.

From the viewpoint of the Spanish-

speaking relevant public, the Court decided there were two principal factors that affected the comparison of the marks:

- The letters v and b were pronounced identically (both as an English "b").
 Accordingly, the respective marks had a high degree of phonetic similarity.
- That public would understand the prefix fem as an abbreviation of the word femenino meaning feminine and therefore the marks would be conceptually similar. The Board of Appeal had thought the conceptual comparison neutral.

Accordingly, the General Court concluded that there was a likelihood of confusion between the marks despite the high degree of attentiveness of the relevant public.

Pharmaceutical prefixes

A quick search on OHIM's database shows a total of 134 Community trade marks covering class 5 goods that start with FEM, 70 of which start with FEMI. However, it is often the case that earlier marks whose similarity with later marks mainly resides in elements of low distinctive character can still be used to block the registration and use of those later marks.

Other recent examples where a likelihood of confusion has been found for goods in class 5 include METABIAREX v METABIOMAK, PROLICO v PROLEC, IMMUNAL v IMMUNOV, PROVAX v PROBAC.

One of the reasons this is a particular issue in the pharmaceutical and life sciences sector is that it is often difficult to establish that the relevant public, and in particular the general public, appreciate the low distinctive character of the elements in common. This is even more the case when, as the General Court confirmed, it is only necessary to establish a likelihood of confusion in one territory of the European Union and therefore the low level of distinctive character effectively needs to be considered across the European Union.

International Update

CROATIA

Gordana Pavlovic, Cabinet Pavlovic

In its judgment of 17 December 2013, the Croatian High Commercial Court ruled that Kras's sale of Mentol sugar-free candies in lilac packaging infringes trade mark for lilac color IR 644464 registered in the name of Kraft Foods Schweiz Holding GmbH (part of Mondelez International Group) for chocolate and products containing chocolate. This is the first time that a Court in that region recognized the distinctive character of the lilac color. The Court held that the trade mark for lilac color IR 644464 is a trade mark with reputation, but that Mondelez did not prove that sale of candies in lilac packaging may harm its reputation or distinctiveness, therefore it did not find infringement on these grounds.

Kraft Foods Schweiz Holding GmbH (part of Mondelez International Group) owns a trade mark for lilac color registered under IR 644464 which is valid in Croatia and used on a range of Milka chocolate products as well as on products made by other companies in co-operation with Mondelez (e.g. Ledo ice-cream).

Kras is a well-known Croatian producer of confectionary products. In their production line they have candies which are sold in the lilac color packaging, featuring the word Mentol, commonly used to designate menthol/mint taste.

Mondelez sued Kras for trade mark infringement and unfair competition. The Court of first instance refused Mondelez's lawsuit. Mondelez appealed to the Court of 2nd instance which ruled in Mondelez's favour as far as trade mark infringement is concerned. The Court held that:

- I) The base of the packaging of Kras's Mentol sugar-free candies is depicted in various shades of lilac color; these shades are similar to the International trade mark registered in the name of Kraft Foods Schweiz Holding GmbH (part of Mondelez International Group);
- 2) the goods at issue are similar, as both candies and chocolate are confectionery products;
- 3) the relevant consumers are consumers of chocolate, which can be with and without sugar, and they are likely to make an association between the contested lilac packaging and Mondelez's lilac color.

Further, the Court held that the trade mark for lilac color is a trade mark with reputation, which enjoys extended protection, against dissimilar goods. However, as the Court held that Mondelez has not sufficiently demonstrated possible damage to reputation or distinctiveness of their trade mark, their claim for infringement of the trade mark with reputation was refused.

This is a huge victory for Mondelez which has been trying to defend its trade mark for lilac color all over the world.

INDIA

Ranjan Narula, RNA Intellectual Property Attorneys

Glaxo Group Ltd (Glaxo) initiated an action before the Delhi High Court for protecting its brand HEPITEC which was being infringed by a Mumbai based company, United Biotech (United) by using the mark HEPROTEC.

Glaxo asserted before the Court that the mark HEPITEC was a coined word having no dictionary meaning. It further argued that the product under the mark HEPITEC is highly popular and has a high degree of reputation and goodwill in India and abroad for treatment of liver related ailments. Glaxo came across the unauthorized use of the mark HEPROTEC by United for treatment of similar ailments related to the liver.

United countered the Glaxo's submissions by contending that the suit had been filed out of trade rivalry as the mark HEPROTEC is neither identical nor deceptively similar with the Glaxo's mark HEPITEC. United in its argument highlighted various features in both products that were different i.e. drug ingredients, form of drug, schedule and manner of sale and price to argue that there was no chance of medicines under the name HEPROTEC being confused with the medicine sold under the mark HEPITEC.

The court, after examining the above issues based on the settled principles of law governing pharmaceutical marks, held that prima facie the mark HEPROTEC of United was deceptively similar to the registered trademark HEPITEC of Glaxo. Court further held that the two marks are phonetically and structurally similar as almost the entire mark HEPITEC has been copied by deleting word "I" and inserting "RO" in the middle.

With respect to the contention of United that the words HEP and TEC are common words used in the trade and no one is entitled to exclusive protection, the court held that no details to the extent of use and date of use was provided and hence the said contention was primarily rejected.

LATVIA

Maija Liberte, Grindeks JSC

On 20 July 2010 Grindeks, JSC, the leading pharmaceutical company in the Baltic States, filed a petition with the Riga Regional court against Olainfarm, JSC, a local Latvian pharmaceutical company, which had registered with the Latvian Patent office the trade mark MIDOLAT in regard to the goods covered in class 5.

Grindeks stated that the trade mark MIDOLAT Μ/ΔΟΛΑΤ is confusingly similar with the well-known in Latvia trade marks MILDRONATS, MILDRONAT (in Cyrillic) and MILDRONATE. The claimant also accused the respondent of unfair competition and requested the court for

the indication of provisional measures of protection.

At the time the claim was filed, the defendant had already started the production of the medicine under the trade mark MIDOLAT, the active substance of which (meldonium) was the same as the active substance of the medicinal product MILDRONATE. Meldonium itself was invented in Latvia as an original preparation for the treatment of cardiovascular diseases. The patent for meldonium owned by Grindeks expired in 2006. Currently MILDRONATE is the most demanded original product marketed and manufactured by Grindeks and is one of the most exported Latvian products.

The request of Grindeks on the indication of provisional measures of protection was satisfied. The medicines marked with the denominations MIDOLAT and MUAONAT of Olainfarm were seized and the respondent was obliged to recall from the course of trade all medication marked with these denominations.

The litigation continued for three more years until in January 2014 the Supreme Court decided to partially satisfy the claim of Grindeks. The court declared invalid the trade mark MIDOLAT ΜΛΔΟΛΑΤ, obliged the defendant to stop the manufacturing and use of the denominations MIDOLAT and ΜΙΔΟΛΑΤ in regard to pharmaceutical preparations, as well as to destroy all the seized medicines, to publish the judgement in mass media and to recover to the complainant the official fees related with this case.

TURKEY

Sema Salman, NSN Law Firm

In a decision dated 9 April 2014, the Constitutional Court has accepted the appeal of the judge of the 4th Istanbul Court of Intellectual and Industrial Rights and unanimously decided to cancel Article 42/1 (c) of the Decree Law no.556.

Said appeal was filed before the Constitutional Court on the ground that non-use among the grounds for invalidation of a trade mark violates the property rights protected with the Constitution because non-use has been regulated both as a ground for cancellation and invalidation and when non-use is evaluated on invalidation grounds, it would have a retroactive effect, meaning that it dates back to the filing date of the non-used trade mark.

Consequently, the retroactive effect of the trade mark right as a property right would violate Article 35 of the Turkish Constitution regulating The Protection of Property Right and in addition to this, although property rights can be limited by law, limitation under Decree Law no.556 violates Article 91 of the Constitution.

Assessment of similarity of European trade marks – Does distinctiveness of the prior mark play a role?

Margret Knitter, SKW Schwarz

It is common, especially in the pharmaceutical sector, to form trade marks from descriptive terms. One advantage of such trade marks is the easier linkage for the user to the medication's field of application.

The following article examines how trade marks formed in such a manner can be enforced in case of infringement according to current European case law.

According to settled case law, the likelihood of confusion is greater, the greater the distinctive character of the prior trade mark. Which at the same time means that trade marks that are inspired by descriptive elements have only a narrow scope of protection. As shown by recent decisions of the European courts, however, this applies only in exceptional cases.

According to settled case-law of the European Court of Justice (ECJ), the global assessment of the likelihood of confusion must, as regards the visual, aural or conceptual similarity of the marks in question, be based on the overall impression created by them, bearing in mind, in particular, their distinctive and dominant elements. It is true that, in certain circumstances, the overall impression conveyed to the relevant public by a complex mark may be dominated by one or more of its components, such that, if all of the other components of the mark are negligible, assessment of the similarity can be carried out solely on the basis of the dominant element. However, it cannot be deduced from that case-law on exceptional situations that only the distinctive element of a mark composed of a descriptive element and a

This was recently held by the ECJ in its CLORALEX decision, where the similarity of the marks CLORALEX and CLOROX was confirmed. The European General Court (GC) approved the Board of Appeal's finding of the distinctiveness of the CLOR element, which is descriptive of one of the ingredients of the goods covered by the mark in respect of which

distinctive element is decisive when

assessing the likelihood of confusion.

registration is sought or forms part of the family of cleaning products. Nevertheless, the Court held that the marks are confusingly similar.

The following decisions show that low distinctiveness of an element in the prior mark does not play a great role when assessing the similarity with another mark.

The marks METABOL and METABOL MG were held to be confusingly similar. The GC held that although the use of the word "metabol" in respect of some of the goods at issue may in fact be regarded as tending to confer on the earlier mark only a weak distinctive character with regard to those goods, the fact remains that the distinctive character of the earlier mark is only one factor among others involved in the assessment of the likelihood of confusion. Thus, even in a case involving an earlier mark with a weak distinctive character, there may be a likelihood of confusion.

The GC also recognised likelihood of confusion between ZIEDCON and figurative mark and CERCON, although the applicant argued that the earlier sign CERCON is taken as an indication of the relevant goods to originate from the dental sector, since a similarity to the word ZIRKON exists as shown in the July 2014 GC judgment. The court made reference to the fact that even if the earlier mark is presumed to have a weak distinctive character, likelihood of confusion would nevertheless exist. The distinctive character of the earlier marks, even if it had to be considered in the assessment of the likelihood of confusion, would only represent one of the factors to be considered in this assessment.

Likelihood of confusion was recognised between the marks FEMIVIA and FEMIBION as detailed further in the article on page 2.

The tendency of the European courts to attach less importance to the distinctive character of the earlier trade marks can also be seen in decisions outside of the pharmaceutical sector. As an example, likelihood of confusion was recognized

between the word and figurative mark "alpine" and the contested application ALPINE PRO SPORTSWEAR & EQUIPMENT, also a word and figurative mark, both covering among other things, goods of classes 18 and 25. The ECJ also saw likelihood of confusion between various prior word and figurative marks with the word component SEVEN and the contested application SEVEN FOR ALL MANKIND, although it was held that the common element SEVEN would possibly only have weak distinctive character.

Summary

Identity to an element that is not capable of being protected may cause likelihood of confusion. This means that what matters most in the comparison of marks is the overall impression of a mark, so that relatively weak, indeed even descriptive elements are also not completely unimportant, because they can still play a role, even if subordinate.

Digression into German law

In Germany, the principle that descriptive components remain disregarded during the assessment of similarity of trade marks and thus do not regularly influence the overall impression of a trade mark, is granted greater importance.

Therefore, the German Federal Patent Court rejected likelihood of confusion of the marks PANTOPREM and PANTOPAN. The court recognized that the beginning syllable PANTO of the opposing mark referred to the active ingredient pantoprazol, a proton pump inhibitor, which is used particularly in gastrointestinal preparations. The relevant public would also recognize this. Therefore, it must be presumed that they would not place their attention primarily on the beginning of the marks, but rather in a particular way also note the additional word components or endings. Thus in this specific case, the differences of the compared marks within the trade mark endings will not remain unnoticed in the aural and typographical overall impression.

Inherent and acquired distinctiveness seen by the Romanian courts

Andra Musatescu, Andra Musatescu Law & Industrial Property Offices, Romania

Nutricia International B.V. (Nutricia), part of the Danone Group, has obtained a second positive final decision in an annulment action brought against a local producer of milk and milk products, S.C. Avi Seb Impex SRL (Avi).

Avi registered a "milapo with device" trade mark



with the Romanian Trademark Office for all the products in Class 29, including milk and milk products, which was annulled by the Bucharest Court of Appeal following a final decision based on procedural issues.

Avi also registered another "milapo with



device" trade mark as shown with the Romanian Trademark Office for all the products in Class 29, including milk and milk products.

Nutricia is the owner of a Community word mark, being registered, inter alia, for "dietetic substances adapted for medical use; food for babies" in class 5 and "milk and milk products" in Class 29; a Community word and device mark as



shown being registered, inter alia, for dietetic substances adapted for medical use; food for babies in class 5 and all

products in Class 29 and finally a class 5



frutapura

Community word and device mark for, inter alia, dietetic substances adapted for medical use; food for babies.

Nutricia considered that its prior trade mark rights were infringed by Avi's registration, especially taking into account the inherent and acquired distinctiveness by use in Romania of the Milupa trade marks and therefore decided to file an annulment action against the registration by Avi of the "milapo with device" trade mark.

Arguments:

Nutricia's arguments in court were extensive, including but not limited to:

- the similarity of the trade marks compared,
- "milapo" being the principal element of the trade mark,
- the existence of a disclaimer for 'cascaval Pintea'.
- the high distinctiveness of the CTMs which was not only inherent, but also acquired by extensive use of the CTMs in Romania evidenced by volume sales, surveys and amount of advertising and marketing undertaken in Romania in connection with the brand.
- the beginning of the trademark being of a high importance,
- the identity for some of the products and the similarity for the remaining of the products for which the trade marks in question were registered,
- risk of confusion and association.

Findings of the court:

In its judgment, the Bucharest Court of Appeal decided to annul the 'milapo with device' trademark because of

- (I) the similarity of the two trademarks based on
- (i) the principle applicable in appreciating the verbal similarity which is that the beginning of the trade mark is of a high importance and taking into account that the compared trade marks have the same prefix 'mil', the trademarks are similar,
- (ii) the disclaimer for 'cascaval Pintea',
- (iii) the insufficient distinctiveness of the device:
- (2) the identity of the products and
- (3) the risk of association is clear as there is the possibility that consumers would consider that there is a link between the previous trade mark and the contested mark.

Comments:

We consider the decision of the Court as of quite high importance, not only for Nutricia which invested large sums of money in establishing a reputation for its Milupa trademarks in Romania, but also as a precedent with regard to the notion of high distinctiveness in Romania.

The decision of the Bucharest Court of Appeal is final and binding following a second appeal filed by Avi at the Supreme Court of Romania which was rejected by the Supreme Court of Romania on procedural grounds on I April, 2014.

The decision of the Bucharest Court of Appeal mentioned above will most probably be followed by other courts.

In this respect, our personal view is that more pharmaceutical and nutritional companies can now take similar actions based on this case and can rely on their previous well-known trade marks or registered trade marks with reputation to request the annulment of other identical or similar trade marks, provided that such identical or similar trade marks are within the 5 years status of limitation period provided by law.

Members News

New Members

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

Merel Kamp of Signify B.V., Amsterdam, The Netherlands merel@signify-ip.nl

Simon Tønners of Chas. Hude, Copenhagen, Denmark st@chashude.com

Yiling Liu of Tsai, Lee & Chen, Taipei, Taiwan yliu@tsailee.com.tw

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Olena Shamrina of Pakharenko & Partners, Kiev, Ukraine elena_shamrina@pakharenko.com.ua

Moves and Mergers

Atsushi Oshima is now with Oshima, Nishimura & Miyanaga in Tokyo, Japan and can be contacted at Oshima@onm-tm.jp.

Martha O'Neill has left Norgine Ltd. to join Walker Morris LLP in Leeds, UK. Martha can be contacted at Martha.oneill@walkermorris.co.uk.

Chris McLeod is now with Squire Patton Boggs (UK) LLP in London, UK. Chris can be contacted at chris.mcleod@squirepb.com.

Asta Uhlbäck is now with Roschier Brands Attorneys Ltd. in Helsinki, Finland. Asta can be contacted at Asta.uhlback@roschier.com.

Perla Kuhn is now with Fox Rothschild LLP in New York, USA and can be contacted at pkuhn@foxrothschild.com.

Patrick Van de Vorst has left Knijff Trademark Attorneys to join Corsearch in Edegem, Belgium. Patrick can now be contacted at Patrick.yandevorst@wolterskluwer.com.

Andrea Klein has left Societa Italiana Brevetti to join Akran Intellectual Property in Rome, Italy. Andrea can be contacted at a.klein@akran.it.

Bernadette Tocjayao has left Veralaw and is now with Virgilaw in Makati City, Philippines. Bernadette can be contacted at bernadette@virgilaw.com.ph.

Sema Salman Sinmez has left Deris Patents and Trademarks Agency to join NSN Law Firm in Istanbul, Turkey. Sema can be contacted at sema.salman@nsn-law.com

Moira Truijens has left Klos Morel Vos to join Hoogenraad & Haak Advertising + IP Advocaten in Amsterdam, The Netherlands. Moira can be contacted at mt@hoogenraad.nl.

Alberto Berton-Moreno Jr is now with Berton Moreno & Asociados in Buenos Aires, Argentina. Alberto can be contacted at abmir@bertonmoreno.com.ar.

Kinga Keleman has left SBGK Patent and Law Offices to join CLV Partners in Budapest, Hungary. Kinga can be contacted at kinga.keleman@clvpartners.com.

Yves Asaert has left Nameshield to join Brandstock Services AG in Munich, Germany. Yves can be contacted at yasaert@brandstock.com.

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, I15 Gregories Road, Beaconsfield, Bucks, HP9 IHZ

Lesley Edwards PTMG Secretary

US Law Update

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

The US Food and Drug Administration (FDA) made available for comment a draft guidance entitled "Best Practices in Developing Proprietary Names for Drugs." According to the draft guidance, the FDA intends for the guidance to help sponsors develop trademarks "that do not cause or contribute to medication errors or otherwise contribute to the misbranding of the drug."

A full article can be read on page 7

The FDA also issued a notice establishing a public docket to discuss issues involving the possible "reservation" of trademarks for new drugs. In its notice, the FDA raised questions and issues to be discussed and asked for comments by 27 October 2014. The official FDA notice can be found in the Federal Register at 79 FR 43751 (28 July 2014).

The US Patent and Trademark Office (USPTO) is proposing to reduce certain application and renewal fees for applications and renewals filed electronically. Electronic applications would be reduced by USD \$50.00 per class under the proposal and electronic applications would be reduced by USD \$100 per class. No change is being proposed in fees for applications and renewals filed on paper. The official USPTO notice can be found at

http://www.uspto.gov/trademarks/notices/statutory_regulatory.jsp.

FDA Releases Draft Guidance on "Best Practices" for Pharma Trade marks

Keith Barritt, Fish & Richardson P.C.

After years of promise, in May 2014 the U.S. Food & Drug Administration (FDA) finally released its long-awaited draft guidance document on "best practices" for developing trade marks for pharmaceuticals, including nonprescription and biological drug products. The draft guidance is designed to help industry adopt trade marks that minimize health risks and potential confusion with other existing marks.

FDA approval of a mark for a pharmaceutical product can be notoriously challenging. Approximately one-third of marks are rejected. The draft guidance document helps to verify the FDA's position and solidify numerous practices of what many in industry have been following for years. Adhering to the draft guidance can maximize the chances that any particular name will win FDA approval.

Recommendations for "Pre-screening" Pharma Trade mark Candidates

The FDA recommends that manufacturers consider the following issues when considering potential name candidates:

- Avoid obvious similarities in spelling and pronunciation compared to existing trade marks, generic names, or ingredient names;
- Avoid incorporating medical abbreviations, dose designations, or symbols that might contribute to medical errors;
- Avoid incorporating reference to inert or inactive ingredients in a way that creates an impression that the ingredient has greater value than it really does;
- Avoid incorporating generic stems in the stem position;
- Avoid "recycling" the trade mark of a discontinued product;
- For fixed combination drug products, avoid trade marks that

include or suggest the name of one or more, but not all, of the active ingredients.

Naming Attributes That Might Be Misleading or Contribute to Errors

After narrowing the list of candidates based on the initial "pre-screening," the FDA recommends manufacturers consider the following characteristics:

- Avoid incorporating productspecific attributes such as manufacturing characteristics ("NameLyophilized"), dosage form ("NameTabs"), or route of administration ("NameOral");
- Avoid modifiers of trade marks ("Name XR") that do not have an established meaning or that otherwise might cause confusion;
- Avoid modifiers that consist of numerals;
- For combination drug-device products, avoid incorporating a device-related modifier into the trade mark that implies the device component operates in a way inconsistent with the modifier;
- Avoid modifiers that are inconsistent with the proposed labeling or otherwise hard for the end user to understand;
- Avoid incorporating the sponsor's name in multiple trade marks;
- Avoid terms that may suggest the product has some unique effectiveness or composition it does not actually have (such as "best").

The use of brand name "extensions", also known as family marks or umbrella names, are evaluated by the FDA on a case-by-case basis, considering whether the products share at least one common active ingredient, are differentiated by labeling, and have appropriate modifiers. The FDA will also evaluate

on a case-by-case basis the use of different trade marks by the same manufacturer for products that contain the same active ingredient but for different indications.

When a product goes from prescription to over-the-counter (OTC), use of the same trade mark may be acceptable if there is no change in indications, dosing, or strength. However, if the OTC and Rx versions are not identical, the FDA believes it "might be appropriate" to market the OTC product under a different or modified trade mark.

The FDA will review a proposed trade mark for an OTC drug that will be marketed pursuant to a New Drug Application or Abbreviated New Drug Application. However, many OTC drugs are marketed under an FDA monograph and are not individually scrutinized by the FDA. For these, the FDA still recommends that the trade marks be evaluated by the sponsor for safety considerations.

Finally, the draft guidance contains detailed descriptions of how the FDA conducts and how sponsors should conduct name simulation studies to try to gauge how likely any given name will cause end-user error based on phonetic, spelling, and orthographic similarities. Although sponsors are not required to submit their own studies, the FDA "believes more comprehensive simulation studies would be useful."

PTMG 90th Spring Conference

Venice

23rd 24th March 2015

Registration will open on PTMG website in mid January 2015

OCTASA v PENTASA: getting the groundwork right

Clare Jackman, Norton Rose Fulbright LLP

On 9 April 2014 the General Court of the European Union (CJEU) annulled OHIM's Board of Appeal earlier decision that the marks OCTASA and PENTASA were not confusingly similar. Essentially, although the asa suffix comprised an acronym for a pharmaceutical's active ingredient, no evidence had been brought to demonstrate that the relevant public, in the relevant territory, would readily perceive the suffix as descriptive of the goods in question. The Board of Appeal were wrong in their decision and the ensuing examination by the General Court of the relevant public and comparison of the respective marks explains why the evidence was found lacking in this case and makes for interesting reading.

Decision

The General Court annulled the Board of Appeal's decision because it could not be established that end users would consider asa, an acronym relating to the active ingredient mesalazine, descriptive of preparations and substances for preventing and treating diseases and disorders of the gastro-intestinal tract.

The General Court found, at odds with the Board of Appeal's decision, that the trade marks are aurally and visually similar by virtue of the shared suffix, which had not been proven to be descriptive. In addition, for those end-users that recognise that the beginnings of the marks in question both refer to Greek numbers, there is also a weak conceptual similarity. The Board of Appeal had also failed to correctly identify the scope of the relevant goods in question and therefore the relevant public. The evidence had not been tailored to take account of the fact that the relevant territory is made up of those member states where the earlier marks are registered, none of which are English speaking states. As a result, nothing of much relevance could be reliably deduced from the evidence.

Background to the dispute

In March 2009, Tillotts filed a community trade mark application for OCTASA for goods in class 5, preparations and substances for preventing and treating diseases and disorders of the gastro-intestinal tract. The active ingredient, mesalazine, is

also known as 5-aminosalicylic acid or simply 5-ASA. Ferring opposed on the basis of its earlier national marks, PENTASA, registered for the broader terms, pharmaceutical preparations and substances in Austria, Hungary, Italy, Poland, Slovakia, Sweden, France, Ireland and the Czech Republic. In April 2011 the opposition division rejected the opposition and Ferring appealed. In September 2012 OHIM's Board of Appeal dismissed the appeal. It held, in essence, that Ferring had more or less shot itself in the foot since it claimed that its extensively used PENTASA product was a pharmaceutical product prescribed for the treatment of diseases of the gastro-intestinal tract, also containing mesalazine. In view of the descriptive character of the suffix asa, the Board of Appeal concluded that there was no similarity between the trade marks PENTASA and OCTASA.

Relevant law: Article 8(1)(b) of Regulation 207/2009

This article provides that, upon opposition by the proprietor of an earlier trade mark, the trade mark applied for is not to be registered if, because of its identity with or similarity to the earlier trade mark there exists a likelihood of confusion on the part of the public in the territory in which the earlier trade mark is protected. The likelihood of confusion includes the likelihood of association with the earlier trade mark. According to settled case law, the risk that the public might believe that the goods or services in question come from the same undertaking or from economically linked undertakings constitutes a likelihood of confusion.

For the purposes of applying Article 8(1)(b) a likelihood of confusion presupposes that both marks are identical or similar and that the goods or services which they cover are identical or similar.

Furthermore, in order to find that there exists a likelihood of confusion for the purposes of Article 8(1)(b), it is not necessary to find that the likelihood exists for the whole of the relevant public – it is sufficient if it exists for a significant part of that public.

The following themes were the focus of the General Court in assessing the

Board of Appeal's contested decision:

The relevant public and its degree of attention

Where the goods in question are medicines, the relevant public is composed of medical professionals on the one hand and patients as end-consumers of those goods on the other. Medical professionals are considered to have a high degree of attention when prescribing medicinal products and it is fair to assume that consumers of such products will also be reasonably well informed, observant and circumspect and are less likely to confuse different versions of such products.

The relevant territory in this case is made up of the member states covered by the earlier trade marks as previously listed. The relevant public comprises medical professionals and patients as the end users. The goods in question which the Board of Appeal considered to be identical include pharmaceuticals in general or, in more specific terms, preparations and substances preventing and treating diseases and disorders of the gastro-intestinal tract.

At the hearing, Ferring claimed that the Board of Appeal had assessed the descriptive character of the suffix asa from the perspective of consumers of an overly narrow category of goods. The relevant public should include consumers of pharmaceuticals in general and not just consumers of medicines containing mesalazine as their active ingredient. As not all disorders of the gastro-intestinal tract are serious illnesses, there would be a large group of consumers who would not necessarily pay such a high degree of attention. The General Court noted that it was not clear from the contested decision which category of goods, medicines in general or medicines with a specific gastroindication, was used by the Board of Appeal in order to determine the relevant public. Nor was it clear what level of attention the Board of Appeal attributed to the relevant public. These findings rendered the decision unreliable.

Comparison of the marks

The General Court found that the Board of Appeal had not established the descriptive character of the suffix asa from the perspective of the end users of the goods in question in the various member states concerned, nor even from the perspective of those end users who were likely to use medicines to treat the diseases of the gastro-intestinal tract which contain mesalazine as their active ingredient.

In the current case, Tillotts had deduced evidence from two online encyclopaedias in English which stated that 5-aminosalicylic acid is a synonym for the active ingredient, mesalazine, and that 5-ASA is an acronym for that synonym. The evidence did not demonstrate that non-English speaking end-users were aware of those names or that they associate those names with the active ingredient mesalazine. Even if the end-users were aware of the names there is no reason to conclude that they would interpret, without further thought, the suffix asa as a description of the active ingredient. As the suffix asa forms only part of the trade marks which consist of a single word, any descriptive meaning which that suffix may have is harder for the end user to make out. In other words, it involves a complex line of reasoning which is at odds with the established principle that a trade mark is descriptive if there is a sufficiently direct and specific relationship between the mark and the goods and services in question to enable the public concerned to immediately perceive, without further thought, a description of one of the

characteristics of the goods or services in question.

No evidence had been brought to show that other pharmaceutical products with the same therapeutic indication and active ingredient 5-ASA were marketed by Tillotts or third parties under names which also included the letter combination asa. Similarly, no evidence was produced of similar trade marks being used in the relevant countries.

The evidence did not establish that medical professionals in the member states concerned use the name 5-aminosalicylic acid, the acronym 5-ASA or the element asa with their patients, or otherwise. Not even a reasonable presumption can be inferred that the suffix asa is descriptive from the perspective of the end users in the member states concerned.

Visual and phonetic comparison of the signs

Although admittedly the first component of word marks is more likely to catch the consumer's attention than what follows, the Board of Appeal was wrong to state that there was no visual or phonetic similarity between the marks. They both end with the suffix tasa. Regarding conceptual similarity – from the perspective of the end users unaware that the suffix asa is a reference to mesalazine - neither of the marks, viewed as a whole, has any

meaning. For end users unaware that the prefixes pent and oct refer to the Greek numbers 5 and 8 respectively, the conceptual comparison is neutral. However, some end-users will recognise the beginnings of the marks refer to Greek numbers. The General Court noted that in certain circumstances different numbers can be conceptually similar if they share common elements. In the present case, the fact that numbers are involved is not the only way in which the signs at issue are conceptually similar - there is also the fact that the numbers are in Greek, a language which is not normally spoken in the relevant territories. That fact is sufficient to support a finding that there is in fact a weak conceptual similarity between the marks.

Summing up

The General Court annulled the Board of Appeal's decision because, on closer examination of the evidence filed in support of the opposition, it found that inadequate attention had been paid in identifying the scope of the relevant goods, the relevant territory and the relevant public and therefore incorrect inferences had been drawn from that evidence. Thus, the General Court, not being satisfied that asa was in fact descriptive or, at least so as to be readily understood by the relevant public, went on to deduce that the marks PENTASA and OCTASA are in fact confusingly similar.

Opposition proceedings in Italy and decisions relative to trade marks claiming class 5

Laura Pedemonte, Barzanò & Zanardo, Italy

Since the entering into force of the opposition proceedings in Italy in July 2011, almost 4,061 oppositions have been lodged with the Italian Patent and Trademark Office (IPTO) and almost 179 decisions have been issued by the latter.

What happened in the practice of the opposition proceedings over the past three years?

Some statistics. Of the decisions issued up to now, around 75% upheld the opposition. The majority of oppositions have been filed by foreign companies and most proceedings were settled by the concerned parties, mainly during the cooling-off period by the withdrawal or the restriction of

the opposed application.

The decisions are issued by the Office within around twenty two months from the filing of the opposition. According to our law, The Office's ultimate decision must be issued within twenty four months from receipt of the notice of opposition (excluding the cooling off period and other eventual suspensions of the proceedings).

So far the IPTO has never requested the parties to file second briefs in opposition proceedings so that the proceedings may be deemed costeffective.

To date, only seven decisions of the

Board of Appeal were recorded in the Register, two of them were upheld. The Board of Appeal is a judicial body and its rulings can be appealed before the Supreme Court.

But what about the decisions relative to trade marks claiming class 5?

Twelve decisions involving trade marks in class 5 have been issued by the Opposition Division and one ruling by the Board of Appeal. Among them, nine oppositions have been upheld (of which three partially) and three rejected. However two of the oppositions upheld have been revoked in a joint appeal by the Board of Appeal.

The merits of the rulings and the assessment of the likelihood of confusion between the trade marks are clearly based on the OHIM case law, obviously taking into account the point of view of the Italian consumers and the local jurisprudence, not always concordant with the OHIM policy.

By examining the said decisions in relation to the comparison between trade marks, it is possible to notice that the assessment process has always been conducted by the Office on the basis of the OHIM principle, acknowledged by our case law, that the evaluation of the likelihood of confusion, as regards the conceptual, aural and visual similarity between the signs, is not an analytical process but it must take into account all the elements of the signs as a whole, considering the distinctive and dominant components, in the way that the relevant consumer would appreciate the mark, relying upon the imperfect image of the latter kept in his memory.

It is also possible to point out two other recurring OHIM case law principles, which may be considered acknowledged by the jurisprudence of the Italian Office.

In particular, trade marks sharing the first (fanciful) part and presenting some similarities in their second portion have been deemed similar on the basis of, among others, the principle that the consumers' attention is focused on the initial part of a trade mark. In fact, the above principle has been recalled and taken into account in deeming the following trade marks respectively confusingly similar in connection with identical or similar goods in class 5:

 TERRAFOR (word) v TERAFLOG (word),

Optima v optima derm crema (word),



In the same sense, the following trade marks, different in their first part, have not been acknowledged confusingly similar in connection with identical/similar goods in class 5: • REDIHALER (word) v EFFIHALER

- RIPACTIVE (word) v



• MEDIFLOR (word) v DELIFLOR

However, the following trade marks, even though they do not share the first element, have been deemed confusingly similar for identical or similar items in consideration of their overall similar impression or of the descriptiveness of their prefix:

- EZEREX (word) v HEREX (word),
- METOPLUS (word) v MEMOPLUS (word),
- EUFLUX (word) v Flux

in this case the prefix EU of EUFLUX has been deemed descriptive for Italian consumers.

Worthy of note is a recent case where trade marks sharing their first element, and presenting similarity in their remaining component, have however been deemed dissimilar in connection with identical/ similar goods in class 5: FORTEZZA v FORTENZA. In this case the marks differ in a single character only but the Opposition Division deemed that the semantic difference between the signs counteracted their visual and aural similarities given that the word FORTEZZA endowed of a clear and specific meaning in Italian so that the public is capable of grasping it immediately.

The other recurring principle in the opposition decisions is that in trade marks formed by both word and device elements, the verbal component remains more imprinted upon the consumer's memory and therefore must be basically considered as the dominant component of the sign. The verbal element has been deemed

dominant in both signs v 19959 men

(deemed similar), in Optima

(deemed similar to OPTIMA DERM

CREMA word), and in both



and respectively v by the Opposition Division. These two last decisions, however, have been revoked by the Board of Appeal which deemed that the central figure in colour, would grasp the consumers' main attention being the dominant element in the

applications and . Also in the

trade mark the device component has been deemed dominant in the mark, preponderant on the verbal element and this played an important role in acknowledging

the difference to RIPACTIVE word mark.

Conclusions and practical tips:

The above picture highlights that the proceedings have been well received, a consistent number of oppositions have been lodged, the great majority of the proceedings are concluded by a settlement between the parties and opposition proved to be cost-effective. The figures show that the majority of the decisions upheld the opposition and this is also notable with reference to trade marks claiming class 5 where around 72% of the oppositions were accepted. Considering that around 28% of proceedings are upheld, it is certainly worth appealing against the decisions when there is no satisfaction with the same.

In light of the above, it is possible to assert that the Italian opposition proceedings may be an incisive and very accessible tool to force the other party to amicably solve the matter or to bar the registration of conflicting marks.

As far as trade marks in class 5 and their protection and enforceability is concerned, it is important to evaluate in advance the risk associated with adopting a trade mark covering class 5 and/or the chances of success in opposition, to take into consideration that marks sharing the first fanciful part and presenting a degree (even not high) of similarity in their remaining component are generally considered to be similar; and that, in order to differentiate a mark from a prior similar word or word-and-device mark, it is crucial to consider a very original and dominant device component. Last but not least, the conceptual difference between the marks, when at least one of the signs is formed by a word endowed of a clear and specific meaning in Italian, would seem to play a decisive role in the assessment of the similarity between the marks, even counteracting possible aural and visual similarities. However future rulings better clarifying what our opposition case law will deem as clear and specific meaning of a word are awaited.

The above conclusions are deduced by the analysis of statistics and a few decisions taken into consideration. However it is too early to assess the real attitude of the Office and in particular of the Board of Appeal and it is necessary to continue to monitor the rulings in order to obtain a clearer picture of the situation.

INNs - Internet Name Nonchalance?

Sarah Wright and Stuart Brooks, Olswang

"The health sector is a major target of those engaged in abusive online cases, e.g. online pharmacies selling counterfeit drugs, and 10% of complaints are filed by the Pharma industry," said the World Health Organisation (WHO) in its 2009 report of the 49th Consultation on International Non-proprietary Names for Pharmaceutical substances (INN Consultation). In this report, the WHO highlighted the vulnerability of the INN system to online abuses, due in part to its uneasy interplay with trade mark rights. Amid significant changes to the Internet system, we consider the relevance of this issue today, what action has been suggested, and the additional challenges on the horizon.

INNs registered as domain names grant their owners a valuable quasi-property right that is contrary to the founding principles of the INN system and raises concerns about consumer safety. In addition, such use can lead to brand dilution or tarnishment, particularly where INNs remain on patent, or where a sole manufacturer is authorised to distribute a drug within a region.

The legal framework

WHO member states agree not to register trade marks or trade names that consist of INNs. However, no equivalent prohibition applies to domain names. In addition, the procedure by which abusive domain names can be challenged or blocked (the UDRP) is not effective against domain names consisting of INNs in the vast majority of cases.

The UDRP complaints procedure, governed by ICANN or one of its approved third party providers, is generally reliant upon three conditions: (i) the existence of an earlier trade mark right which is confusingly similar or identical to the domain name; (ii) a lack of legitimate rights or interests in the domain name by the registrant; and (iii) the bad faith registration or use of the domain. Previous UDRP complaints have sought to rely on a domain's confusing similarity to an INN instead of a trade mark. However, as explained in Teva Pharmaceutical Industries Limited v BLTC Research, the non-proprietary nature of INNs means they fall outside the meaning of a trade mark for the purposes of UDRP policy.

This means pharmaceutical companies are unable to use the UDRP system to take action against a domain name which is identical to an INN, even if possessing a monopoly right over production of the INN, through patent rights, for example.

Solutions explored

After substantial consultation, WIPO's Second Internet Domain Name Process proposed in 2001 that ICANN should firstly prohibit the registration of new domain names identical to registered INNs, and secondly provide a simple administrative verification procedure through which third parties could seek cancellation of domains consisting of INNs. However the WIPO General Assembly did not support this recommendation. The WHO, taking on the mandate in its 49th INN Consultation "to promote and protect INNs" and "to prevent registration of INNs as domain names" wrote to ICANN in December 2009 and again in April 2010 urging it to take (unspecified) appropriate measures to protect INNs before moving forward with the planned expansion of the list of Generic Top Level Domains (gTLDs).

The current position

Five years on, we approach the 59th INN Consultation with no reported response from ICANN. The expansion of gTLDs continues apace, and there remains no uniform mechanism by which abuses of the INN system through domain names can be efficiently prevented or resolved.

Meanwhile the increasing use of INNs in drug prescriptions and on generic pharmaceuticals has exposed consumers to INNs without necessarily educating them about their non-proprietary nature. Ever greater numbers of consumers are also spending more online, with online sales topping USD \$1 Trillion in 2012, and increasing each year since. This opportunity has sparked exponential growth of online pharmacies around the world. While regulatory procedures are designed to protect consumers, these have failed to keep up with the eversophisticated threats posed by unscrupulous online pharmacies. The lack of an adequate mechanism to block use of INNs as domain names therefore presents a choice opportunity for illicit actors. As consumers' familiarity with INNs

increases, so too does the extent to which they are likely to perceive domain names consisting of INNs to signify authenticity.

As ICANN continues to increase the number of available gTLDs, NetNames predicts a step-change in the way users access websites, which may compound this problem. In particular, as parts of web addresses take on more consumer-facing meanings e.g., .london for local results, .tech for gadgets etc., direct search is predicted to become more popular. Some pharmaceutical companies have adopted the strategy of pre-emptively registering domains in order to block would-be illicit actors from reflecting INNs in domain names. However, this approach is far from perfect, requiring constant monitoring, significant financial outlay and offering no guarantee that all targeted behavior can be blocked. The increasing number of gTLDs under which INNs can now be registered will render this strategy even less effective.

One strategy mooted by WHO to overcome these issues is the promotion of a new regulated gTLD, such as .health as the go-to registry for verified and impartial consumer health information. However, in a characteristic display of internet irony, the right to .health was bid upon exclusively by four private, for-profit companies, sparking third party objections from the French government, International Medical Informatics Association and the European Commission Communiqué. Two private applicants have managed to overrule these objections and will now proceed to bid for the gTLD by auction. In overturning one decision, panellist Jan Paulsson acknowledged concerns that the USD \$185,000 minimum investment in the gTLD might lead to commercial interests prevailing over consumer protection, but dismissed them as "undisguised bias against commercial applicants" which did not permit him to object to the bids under ICANN's policies.

Against this backdrop, it is clear that ICANN sees its role as confined to protecting commercial interests. Perhaps then it is time to revisit measures to safeguard the correct operation of the INN system - and the health of consumers - online.

PROFILE: Pat Berry

Pat Barry, a long standing PTMG member has recently retired from law firm Abel & Imray.

"When I first headed the Trade Mark team at Abel & Imray, I had very little practical trade mark experience. Essentially, therefore, I had been dropped into the deep end. The firm had several major pharmaceutical companies as clients and much of our work for them was conducted by telephone. Instant advice was required on major issues. I often had nightmares of having missed some fundamental point. I survived, not least because I was surrounded by an excellent team — an absolute prerequisite for any aspiring attorney. Throughout my career I have been fortunate to have had that essential support".



Where were you brought up and educated?

Born in South East London. Educated at Alleyn's School, Dulwich and Durham University.

How did you become involved in trade marks?

Not by design. I joined Abel & Imray in 1964 as a graduate in Physics and qualified as a patent attorney. However, I always had an interest in trade marks and later, after becoming a partner, I volunteered to head the Trade Mark team.

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

Medicine has always been a fascination and so, probably, a medical practitioner.

Which three words would you use to describe yourself?

I would like to think others viewing me as being: diligent; resolute; receptive.

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

Mathematics

What does all your money get spent on?

Ask the Missus!

What is your biggest regret? tempus fugit

What is your favourite work of art?

Van Gogh's Sunflowers

Whom do you most admire and why?

Nelson Mandela for his generosity of spirit.

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

Miles Davis box set.

How do you relax?

Rarely!

Which sport do you play and/or enjoy?

Football

What is your all-time favourite film?

Some Like It Hot

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

Melvyn Bragg

What is your favourite drink? I.P.A.

What is your favourite holiday destination?

Ireland.

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

Ban parking meters.

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

St Paul's Cathedral – it's timeless

What's the best invention ever?

Printing press

Which modern convenience could you not live without?

Electricity

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