‘Trade Marks of Pharmaceutical Products in the European Legal System’

Workshop ‘Pharma 1’
AIPPA 5-11 September, Helsinki

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Plan of presentation

1. Trade marks registration systems available in Europe,

2. Genuine use with respect to pharmaceutical trade marks

3. Assessment of the infringement of a right to a trade mark - issues determining the likelihood of confusion
   - relevant public/the average consumer of the products,
   - comparison of goods and services,
   - comparison of signs.

4. EMA (European Medicines Agency) – scope of assessment of a pharmaceutical trade mark

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TM registration systems available in Europe

- **National trade mark registration system**
  performed by national authorities (e.g. Patent Office in Poland, INPI in France – Institut National de la Propriété Industrielle)

- **IR-Mark – the ‘Madrid system’**
  for the international registration of marks established in 1891 and functioning under the Madrid Agreement (1891), and the Madrid Protocol (1989), administered by the International Bureau of WIPO located in Geneva, Switzerland.

- **CTM – Community Trade Mark**, registered by OHIM (Office For Harmonization In The Internal Market, located in Alicante, Spain) on the basis of Council Regulation (EC) No 207/2009 on the CTM (hereafter: CTM Regulation).
Premises of CTM registration

- **Absolute grounds for refusal are always assessed by OHIM (art. 7 of the CTM Regulation).**
  - e.g. the word CTM *Vektor-Lycopin* was rejected because of lack of distinctive character and its solely descriptive character for the German- and English-speaking public of the EC as for goods in class 5, 29, 30 in respect of which registration was sought - Art. 7.1.(b) and (c) of the CTM Regulation (case T-85/08, 9/07/2010, Exalation Ltd. v. OHIM)
  - principle of **uniform character of CTM protection** (obstacle concerns only one country of EC = rejection of the whole CTM registration)

- **Relative grounds for refusal** – a conflict with another earlier trade mark can be investigated by OHIM only as a result of opposition submitted by the owner of the earlier mark (art. 8 of the CTM Regulation)

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Consequences of the lack of a CTM ‘genuine use’ - crucial issue for pharma TM

- **Art. 15.1 CTM Regulation:**
  
  - ‘If, within a period of five years following registration, the proprietor has not put the Community trade mark to *genuine use* in the Community in connection with the goods or services in respect of which it is registered, or if such use has been suspended during an uninterrupted period of five years, the Community trade mark shall be subject to the sanctions provided for in this Regulation, unless there are proper reasons for nonuse.’

  - The above mentioned sanction is the revocation of the right to a trade mark (art. 51.1.(a) CTM Regulations).

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In general, the intention of use and preparatory activities are not genuine use of a trade mark. However, preparatory activities are taken into consideration with regard to the evaluation of the genuine use if they have external character.

According to the OHIM decision, the examples of such activities are:

- the reference to the products in the *Indice Nacional Terapêutico* (it must be regarded as a form of advertising),

- the price authorization.

**Doubt:** Can we presume that according to this decision, *clinical trials* shall be interpreted also as the activities that create a genuine use of a trade mark?
To retain a CTM registration until gaining the authorization of a medicine the owner can:

- **defer the date of filing** the application for a CTM (it is good to wait until the last stage of clinical trials),

- submit a **re-application** of the same CTM (repeated application) – risk of the bad faith allegation!

The Guidelines relating to proceedings before OHIM (Part D, Section 2, paragraph 4.3.3) contains the following assumption:

‘Where the proprietor of a CTM makes repeated applications for the same mark with the effect of avoiding the consequences of revocation for non-use of earlier CTMs, whether in whole or in part, the proprietor is acting in **bad faith**.’

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Genuine use of CTM – ways of using

- In order to determine whether the applicant is acting in **bad faith** for the purposes of Article 52.1(b) of Regulation No 207/2009, account must be taken of **all** the relevant factors (Court of Justice of EU, case C-529/07 Chocoladefabriken Lindt & Sprüngli):

  o the fact that the applicant knows or should know that a third party is using, in at least one Member State, an identical or similar sign for an identical or similar product liable to be confused with the sign for which registration is sought;

  o the applicant’s intention of preventing that third party from continuing to use such a sign;

  o the degree of legal protection enjoyed by the third party’s sign and by the sign for which registration is sought.

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Genuine use of CTM - territorial scope of use
(C-149/11, 19-12-2012, Leno Marken BV v. Hagelkruis Beheer BV, TM: ONEL)

- ‘Article 15(1) must be interpreted as meaning that the territorial borders of the Member States should be disregarded in the assessment of whether a trade mark has been put to ‘genuine use in the Community’ within the meaning of that provision’.

- ‘A Community trade mark is put to ‘genuine use’ within the meaning of Article 15(1) when it is used:
  - in accordance with its essential function and
  - for maintaining or creating market share within the EU for the goods or services covered by it.’

- The member state court needs to decide whether the conditions of CTM use were met on a case-by-case basis

- Conclusion: what was predictable - simple test of territorial use - has now become confusing and unpredictable.

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Genuine use of CTM – form of use
(case C-252/12 of 18/12/2013, Specsavers and parallel judgment C-12/12, Colloseum Holding v. Levi Strauss & Co.)

Genuine use within the meaning of Article 15.1 ‘may be fulfilled where a Community figurative mark is used only in conjunction with a Community word mark which is superimposed over it, and the combination of those two marks is, furthermore, itself registered as a Community trade mark, to the extent that the differences between the form in which that trade mark is used and that in which it was registered do not change the distinctive character of that trade mark as registered.’

<table>
<thead>
<tr>
<th>registered trade marks</th>
<th>Used trade mark</th>
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<tr>
<td>Specsavers (word trade mark)</td>
<td>![Specsavers logo]</td>
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‘Article 9(1)(b) and (c) of CTM Regulation must be interpreted as meaning, that where a Community trade mark is not registered in color, but the proprietor has used it extensively in a particular color or combination of colors with the result that it has become associated in the mind of a significant portion of the public with that color or combination of colors, the color or colors which a third party uses in order to represent a sign alleged to infringe that trade mark are relevant in the global assessment of the likelihood of confusion or unfair advantage under that provision.’
Assessment of the infringement of a right to a trade mark
(on the basis of the judgments of European courts and OHIM decisions)

Issues determining the likelihood of confusion
(art. 9.1(b) CTM Regulation):

1. relevant public/the average consumer of the products,

2. similarity of goods and services,

3. similarity of trade marks.

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General definition of the customer

The average consumer is deemed to be ‘a reasonably well informed, reasonably observant and circumspect person.’

The average consumer’s level of attention is likely to vary according to the category of goods or services in question.

Case C-342/97 Lloyd Schuhfabrik Meyer, 22/06/1999
The average consumer with regard to the OTC-medicines (over-the-counter-medicines)

- healthcare professionals (doctors, nurses, pharmacists) and
- average end-consumers (without any medical or pharmaceutical knowledge)

  - decision of the Bord of Appeal of OHIM (hereafter: BoA) of 04/02/2004, R 987/2002-1
  - case T-256/04, RESPICUR v. RESPICORT, 13/02/2007

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The average consumer in the case of prescription-only-medicines (two approaches)

- only highly qualified, specialised professionals according to the former case-law
  - BoA Case R 304/2003-1, RIBOMUNYL v. RIBOMUSTIN
  - BoA Case R 1154/2000-4, QUARTAMIN v. TAMIN
  - BoA Case R366/2001-4, MEDREL v. MEDROL

- both healthcare professionals and end-users (patients) according to the latest case-law
  - case T-222/09, ALPHAREN v. ALPHA D3, 9/2/2011
  - case C-412/05 TRAVATAN v. TRIVASTAN, 26/4/2007

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I. The average consumer in the case of prescription-only medicines: only highly qualified, specialised professionals

- OHIM BoA Case R 304/2003-1, RIBOMUNYL v. RIBOMUSTIN
  - not everyday goods but used for the treatment of very specific and serious diseases, sold on prescription (i.e. pharmaceutical preparations for immunotherapy),
  - The relevant public is composed of highly qualified, specialised professionals (doctors, nurses, pharmacists)
  - Likelihood of confusion is reduced and even small differences, as e.g. differences in one letter may be enough to exclude confusion.

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II. The average consumer in the case of prescription-only-medicines: both healthcare professionals and end-users

- Judgment of General Court, 9 February 2011, Ineos Healthcare Ltd v. OHIM & Teva Pharmaceutical Industries Ltd, T-222/09
  - Later word CTM ALPHAREN v. earlier national word mark ALPHA D3”
  - ‘Even though the choice of those products is influenced or determined by intermediaries, a likelihood of confusion can also exist for consumers since they are likely to be faced with those products, even if that takes place during separate purchasing transactions for each of those individual products, at various times.’

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The threshold of attention of an average consumer in relation to pharma products when assessing the likelihood of confusion

- **if only healthcare professionals:**
  - higher threshold of attention

- **if both healthcare professionals and end-users (patients):**
  - normal threshold of attention (C-412/05 TRAVATAN v. TRIVASTAN, 26/04/2007 (case related to prescription-only medicines: ophthalmic pharmaceutical products))
  - higher threshold of attention because of serious diseases and side effects (T-256/04, RESPICORT v. RESPICUR, 13/02/2007 (case related to prescription-only medicines and OVC-medicines) (‘Since many respiratory illnesses are serious conditions, patients suffering from those illnesses (…) generally showing a higher than average level of attention’) and BoA of 25/11/2003, R-151/2002-2, RESPIR v. RESPERO)
  - ‘Degree of consumer attention might be very low in the case of certain types of OVC-medicines for mild disorders and minor afflictions such as painkillers, sleeping pills, healing ointments’ (BoA of 25/04/2001, R- 816/1999-3, A-MULSIN v. AIMOXIN)
Similarity of signs – general rules

- The global assessment of the likelihood of confusion, as far as it concerns the **visual, phonetic or conceptual similarity** of the opposing signs, must be based on the **overall impression** given by the signs, bearing in mind, *inter alia*, their distinctive and **dominant elements**
  - Case T-292/01 *Phillips-Van Heusen v OHIM* [2003] ECR II-4335,
  - Case C-334/05 P *OHIM v Shaker* [2007] ECR I-4529).

- **The consumer generally pays greater attention to the beginning of a mark than to the end**

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‘Visual similarity of marks is of lesser importance than the phonetic one’, having in mind that pharmaceuticals are in general (except for very harmless medicines as painkillers or dietary supplements) not bought in self-service-stores but in pharmacies where the consumer has to actively demand a certain medicine from the pharmacist

- BoA decision, case R- 304/2003-1 RIBOMUNYL/RIBOMUSTIN

**Comment:**

This thesis can be questionable as far as the on-line pharmacy is concerned!

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Similarity of goods as for the pharma products

- According to the OHIM (the Manual concerning opposition, Chapter 2: ‘Comparison of goods and services’),

- products similar to pharmaceuticals are:
  - cosmetics,
  - dietetic foodstuff and substances,
  - food for babies,
  - sanitary preparations,
  - disinfectants.
Assessment of Pharma trade marks by Authorities

- Trade Mark Offices
  - OHIM (Office For Harmonization In The Internal Market)
  - National Trad Mark Offices

- Health Authorities
  - EMA (European Medicines Agency)
  - National Health Authorities
    (e.g. FDA (U.S. Food and Drug Administration))

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Legal basis for a trade mark assessment by EMA (European Medicines Agency)

- The 5th update of EMA guideline of December 11, 2007 on the acceptability of names for human medicinal products processed through the centralised procedure.

- The 6th update currently under review

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Principles of a trade mark assessment by EMA according to the 5th update of EMA guideline

- EMA is obliged to ‘consider whether the invented name proposed for a medical product could create a public health concern or potential safety risk’.

- The ‘invented name’ (a trade mark) of a medical product should not:
  - be liable to cause confusion in print, handwriting or speech with the invented name of another medical product,
  - convey misleading therapeutic or pharmaceutical connotations,
  - be misleading with respect to the composition of the product,
  - be liable to confusion with INN.
Scope of a pharma trade mark assessment as for the likelihood of confusion

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<tr>
<th>Trade Mark Offices (OHIM and national offices)</th>
<th>Health Authorities (EMA)</th>
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<tr>
<td>Evaluation of likelihood of confusion between trade marks in respect of origin of goods or services</td>
<td>Evaluation of likelihood of confusion between invented names in respect of safety issues as to the use of pharmaceutical products</td>
</tr>
<tr>
<td>Assessment of another entity IP rights infringement</td>
<td>No assessment of another entity IP rights infringement</td>
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Examples of rejected trade marks

- **OHIM**
  - **SANTARIS PHARMA A/S** was rejected because of **SANTIS PHARMA AG**
    - likelihood of confusion (Opposition 12114, October 30, 2012).
      The differences were unlikely to exclude the likelihood of confusion even though the products with a trade mark were purchased with a higher degree of attention.
  - **CLOPIN** vs. **CLOPACIN** no likelihood of confusion (Opposition 12284, November 6, 2012).
    The board found that the phonetic differences between the marks were sufficient to exclude the likelihood of confusion because consumers usually purchase pharmaceuticals with a higher degree of attention.

- **EMA**
  - **CAMPATH** was rejected because of **CAMPTO**
    (CAMPATH turned into MABCAMPATH)

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Thank you for your attention

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