SANOFI

Pharmaceuticals - Creation and Clearance of Brand Names

Joëlle SANIT-HUGOT – Principal Counsel

Pharmaceuticals Names

Trademark / Brand Name

Common name = INN (International non-proprietary name) – **Stem =** pharmacological properties **-grel** (platelet aggregation inhibitors)

Focus = Naming of new innovative medicines

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The challenge for pharmaceutical branding

Multi-layered examination by authorities

Trademark Offices review

Traditional TM Examination process

Health Authorities review

Stringent assessment process / varying approaches and standards

Two processes completely independent of each other

No consideration of TM registrations by Health Authorities

GLOBAL BRAND
Single Brand Name worldwide

PATIENT SAFETY

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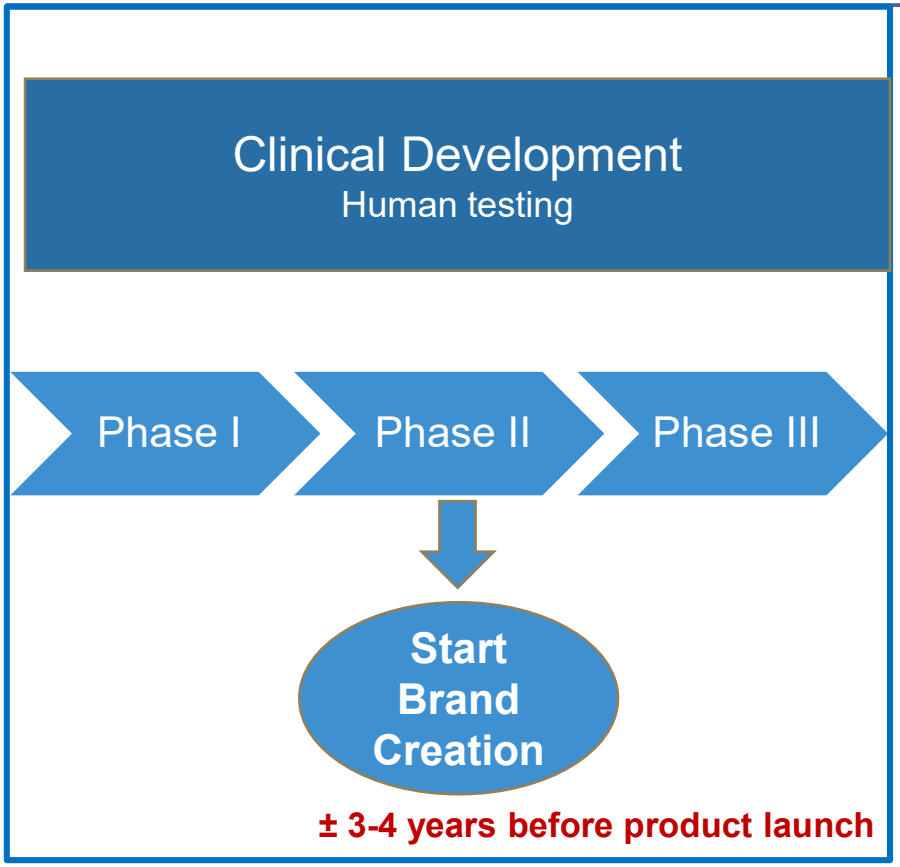
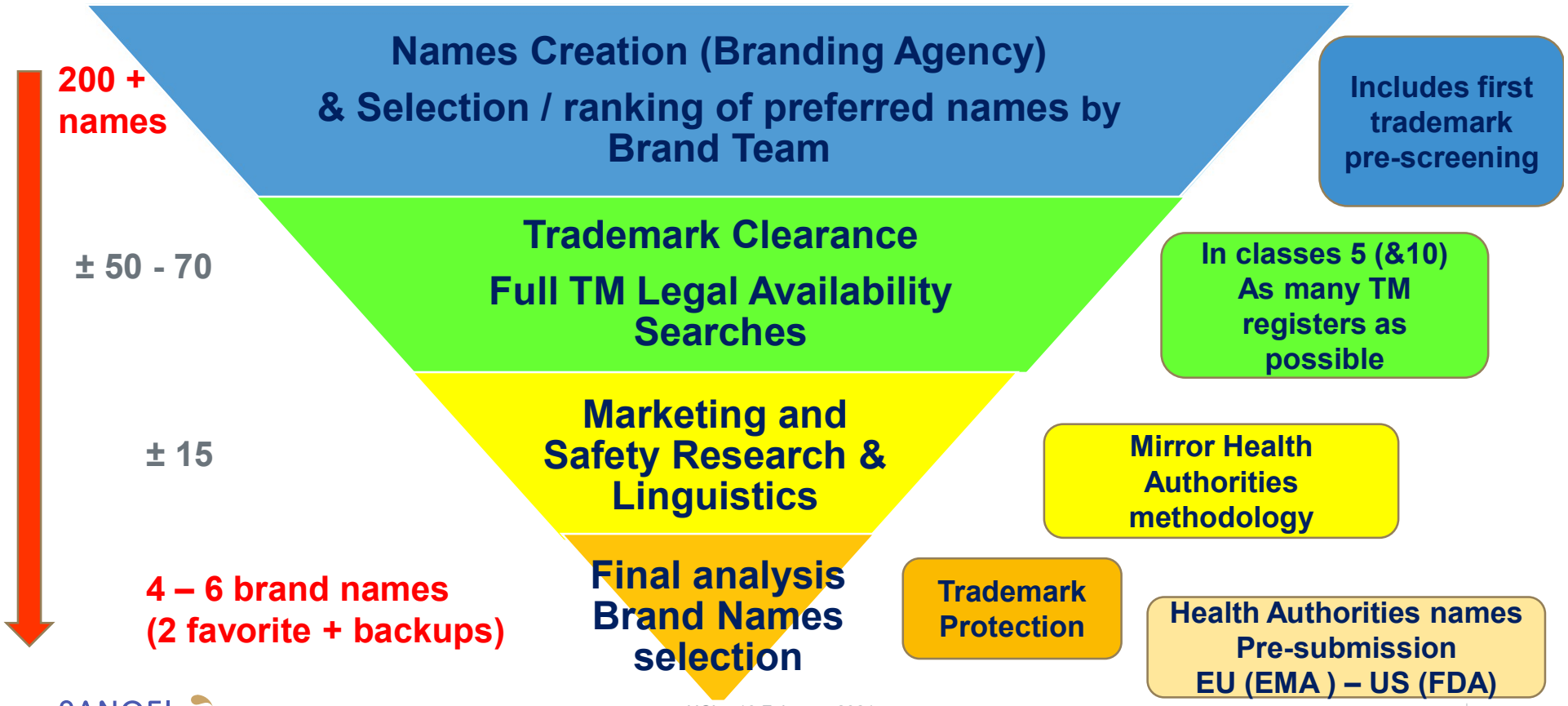
Branding Process for pharmaceuticals (new innovative medicines)



Creation process for Global Pharmaceutical Trademarks



Names Creation

- **Creative process – Methodology**
  - Product overview / target market patients
  - Competitive landscape
  - Creative directions / concept - ideas to promote

Different brand names styles (examples)

Indication / Therapeutic area

COMIRNATY® (covid-19 mRNA vaccine – **Pfizer & BioNTech**) - Combination of the terms COVID-19, mRNA (messenger RNA technology), community and immunity

Attribute / Benefit

LUCENTIS® (ranibizumab – **Genentech & Novartis** – Treatment of certain sight problems caused by damage to the retina) – Encodes reference to « luce » / lucent

Names Creation

Aspirational / imaginery indicative

VIZIMPRO® (dacomitinib – **Pfizer** - Cancer medicine to treat adults with non small cell lung cancer) – « impro » refers to "possible life improvement"

VICTOZA® (liraglutide – **Novo Nordisk –** Treatment of diabetes) – Evokes « victory »

Blank Canvas / Empty vessel

PRALUENT® (alirocumab – **Sanofi & Regeneron –** Medicine for lowering levels of fat in the blood)

GILENYA® (fingolimod – **Novartis** - Treatment of Multiple Sclerosis)

Names Creation – Compliance with Trademark criteria
Absolute grounds for refusal – Article 7 EUTMR

- **Trademark should be distinctive / not descriptive -** Art. 7 (1) (b) & (c)
  - **Trademark should not be derived from INNs + No use of stem**
    WHO (World Health Organization) Resolution WHA 46.19 – May 1993 - "Soft law"
- **Trademark should comply with public order and morality -** Art. 7 (1) (f)
- **Trademark should not be deceptive / misleading** (as to nature, quality …) Art. 7 (1) (g)

Trademark Clearance / Availability searches – Criteria to apply

- **Trademark should be « available » : not infringe third parties' earlier rights** *(mainly trademark rights)* – Art. 8 (1) (b) – EUTMR

  - New candidate trademark should not be :
    - identical or
    - **confusingly similar** – *overall impression / visual, phonetic, conceptual appreciation / analysis of distinctive and dominant components*

  To

    - Earlier third party's **Trademark rights** - Δ *distinctiveness*
    - Identifying **identical or similar goods**

Trademark Clearance / Availability searches - Criteria to apply

Goods

Searches conducted in Class 5 (pharmaceuticals) **(+ Class 10** – medical apparatus**)**

- **Trademarks databases** in **Class 5** = **overcrowded**

- **« Pharmaceutical preparations » includes as "identical goods"**:
  - Veterinary preparations, herbal and homoeopathic medicines, testing preparations (i.e. chemical reagents for medical & veterinary purposes)

- **Similarity of goods in pharmaceutical area** (EUIPO Guideline)
- **Specific pharmaceuticals** are **similar** to other **specific pharmaceuticals**

Trademark Clearance / Availability searches – Criteria to apply

- BUT **degree of similarity** may vary depending on the **specific therapeutic indications**
  - Ex. Sedatives vs pain killers = **highly similar**
  - Ex. Anti-epileptics vs pharmaceutical preparations, except medicines to combat diseases in connection with the central nervous system= **similar**
  - Ex. Cardiovascular preparations versus pharmaceutical preparations for the treatment of central nervous system diseases.= **similar to a low degree**

- Pharmaceuticals and **dietetic substances** adapted for medical use = **similar**
- Pharmaceuticals vs **cosmetics** (with medical properties) **= similar**
- Pharmaceuticals and **plasters** = **similar**

Trademark Clearance / Availability searches – Criteria to apply

- **Relevant public to consider**
  - **General public** (consumers / patients) – ***more prone to confusion***

and

  - **Health professionals** (doctors and pharmacists)

- **Degree of attention**
  - **High / relatively high** degree of attention of the relevant public
    - For pharmaceuticals sold under prescription or not (OTC products)
    - "Pharmaceutical goods affect the "**state of health**"
  - EU case law trend = **Likelihood of confusion more restrictively interpreted**

To be balanced with Health Authorities assessment criteria & patient safety

➡ **Apply cautious stance** when conducting TM availability searches

Trademark Clearance Process for Global Brand
Key role of in-house Trademark Attorney

- **Trademark Attorney to define availability searches strategy :**
  - **Searches to be conducted across a large number of regions**
  - **Via « cascade » approach** (to minimize costs) = step-by-step elimination process
    - Identification of a prioritized list of Countries / Registers
    - (1) Global Pharma-In-Use data (IMS Health) – (2) TM Registers for « survivors »

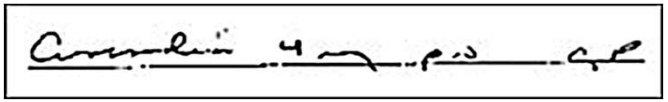
- **Trademark Attorney to compile searches results & to prepare a consolidated report with ratings of names by level of risk**
  - **LOW =** *no serious legal obstacles identified*
  - **MEDIUM =** *names may be subject to challenge but appear legally defensible*
  - **HIGH =** *unavailable*

Challenge = Similarity assessment / Multi-countries approach

Thoughtful Risk-Taking

Marketing & Safety Research (in collaboration with Branding Agency)

- **Participation of Health Professionals** (*Medical practitioners, Specialists, Nurses, Pharmacists)* **in specific countries**

- **Safety Testing / Research - Regulatory measurements** (mirror Health Authorities review process) **= Avoid brand names confusion**
  - **New brand names' similarity assessment** - versus
    - Marketed pharmaceuticals and INNs
    - Medical terms or abbreviations
  - **Prescription simulation study** 
    - Interpretation of written, verbal and computerized prescriptions
  - **New brand names Quality assessment**
    - Inappropriate / Exaggerative / promotional claim identification

Marketing & Safety Research (in collaboration with Branding Agency)

- **Market Research - Commercial measurements of new brand names**
  - Fit to product concept / to therapeutic area ?
  - Marketing Attribute / benefit evaluation
  - Memorability
  - Ease of pronunciation
  - Health Professionals' personal preferences

Linguistics (in collaboration with Branding Agency)

- **Linguistic screening**
  - In major world languages (40+ languages worldwide for a Global Brand)
  - To identify : pronunciation issues / negative connotations, associations, slang

Brand Names / Trademarks Final Selection

- **Brand Team to review :**
  - Brand Names / Trademarks Availability Searches Report
  - Marketing and Safety research (& Linguistics) Report
- **Selection of brand names (most promising) for submission to Top Management (identification of 2 favorite names and backups)**

- **Brand names filing / registration at Trademark Offices**
- **Brand names pre-submission at FDA (USA) & EMA (EU)**

Thank you for your attention
Questions ?

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA perspectives on the review of invented names

Presented by Alexios Skarlatos
Head of Labeling, EMA

1. Legal basis – Single name rule – Centralised procedure

- Article 6(1) of Regulation (EC) No 726/2004: '*…shall include the use of a single name for the medicinal product.*'

- Article 1(20) of Directive 2001/83/EC : '*Name of the medicinal product: The name, which may be either an invented name not liable to confusion with the common name, or a common or scientific name accompanied by a trade mark or the name of the marketing authorisation holder.*'

Exception from the rule of single name

EUROPEAN MEDICINES AGENCY

- **Article 6(1) of Reg. 726/2004**

Deviation from the rule of a single name is allowed in exceptional cases relating to the application of the law on trade marks.

Very rare scenario => requires European Commission's involvement => only twice applied in the history of NRG.

Name Review Group (NRG)

- One of the oldest working groups (est. in 1999) set up to review (invented) names of medicinal products being assessed by the Agency.

- Composed of ≈50 contact points in all Member States; of those, 15 regular attendees representing the main language groups + an expert on patient safety

Language family	Member States	Population (millions)
Romance	IT, FR, ES, PT, RO	180.7
Slavic	BG, PL, CZ, SK, SI, HR	89.5
Baltic	LT, LV	13.9
Greek	EL, CY	12
Semitic	MT	0.4
Uralic	HU, EE, FI	16.6
Germanic	BE, DK, SE, UK, IE, LU, DE, NL, AT, IS, NO	195.4

+ 1 expert on patient safety

EC and WHO consulted on a case-by-case basis

Role

To consider whether the (invented) name proposed by a product's manufacturer could create a public-health concern or potential safety risk.

- Confusion with existing medicinal product
- Misleading therapeutic/pharmaceutical connotations/composition
- Promotional names
- Offensive / inappropriate connotation
- Protection of INN/INN stems

To prevent name-related medication errors

NRG secretariat – What do we do?

Applicants propose names

- *NRG secretariat handles and validates requests and creates Agenda ensuring consistency and accuracy.*

NRG contact points (50) review proposed names and submit objections

- NRG secretariat reviews consistency and accuracy

NRG (15) discuss objections + provide acceptability outcome

- NRG secretariat provides support during discussion and prepares minutes and ToD.

CHMP endorses outcome

- NRG secretariat presents Table of Decisions for adoption.

Communication to applicants

- Preparation and dispatch of outcome faxes.

If name rejected

Possibility to appeal NRG/CHMP position

3-month process – 6 times a year

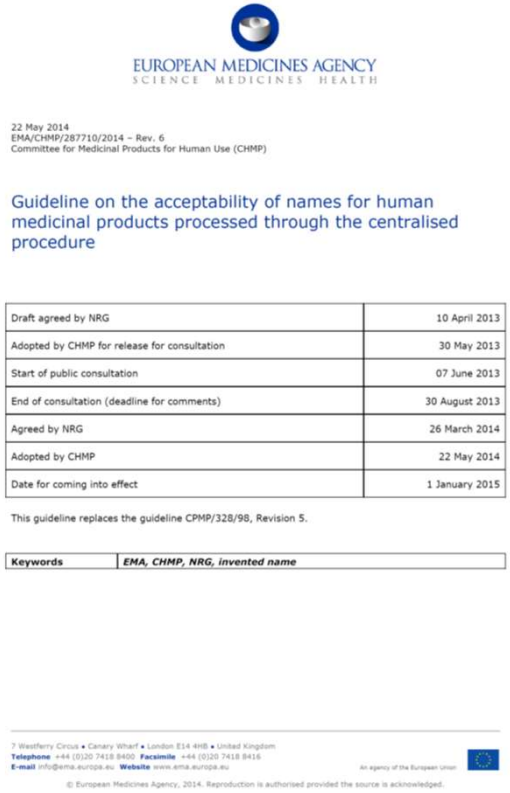
"NRG guideline"

Defines the criteria used by the group to reach a positive or negative outcome:

- **Submission rules – up to 2 names**
- Requirements for acceptability

• Use of **checklist for the decision making** when discussing the **link between orthographic/phonetic similarity and potential for medication errors**

Aim: For a streamlined decision making with more substantiated and transparent name review outcomes.



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

22 May 2014
EMA/CHMP/287710/2014 – Rev. 6
Committee for Medicinal Products for Human Use (CHMP)

Guideline on the acceptability of names for human medicinal products processed through the centralised procedure

Draft agreed by NRG	10 April 2013
Adopted by CHMP for release for consultation	30 May 2013
Start of public consultation	07 June 2013
End of consultation (deadline for comments)	30 August 2013
Agreed by NRG	26 March 2014
Adopted by CHMP	22 May 2014
Date for coming into effect	1 January 2015

This guideline replaces the guideline CPMP/328/98, Revision 5.

Keywords	*EMA, CHMP, NRG, invented name*

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Acceptability rates of (invented) names

2020 acceptance rates: 52% (IN & INN + MAH)

Conditional acceptability

Conditional acceptability means that similarity in print, speech and handwriting is endorsed with accepted (invented) names valid in NRG database used or not used in ongoing marketing authorisations.

Invented names of pending submissions are not disclosed. Applicants have the possibility to enter into bilateral negotiations with the MAH of the clashing name (provided there is agreement of both parties) via the NRG secretariat.

Specific issues

EUROPEAN MEDICINES AGENCY

- Increasing trend of invented names including parts of the name of the sponsor as an umbrella segment
- Fixed dose combination name proposals in relation to the approved names for the mono-component
- How differences in national practices affect NRG decisions (prescription/dispensing)
- INN similarity as a reason for rejection
- Use of Phonetic and Orthographic Computer Analysis (POCA) program in the NRG review
- Article 57 research tool – poorly researched names => unnecessary workload
- Inclusion of the whole name of a medicine in the newly proposed one.
- Pronunciation as a ground for rejection

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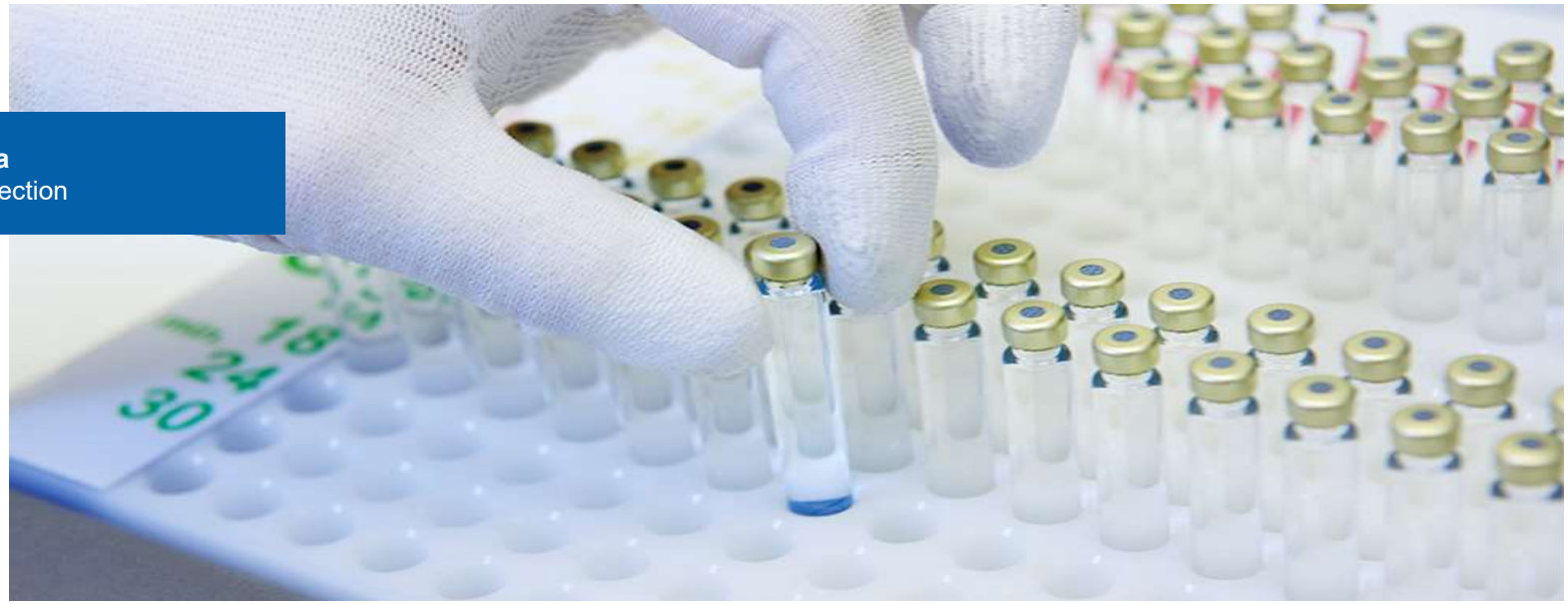
Novartis Pharma
Legal Brand Protection



OPPORTUNITIES & CHALLENGES FOR NON-TRADITIONAL PHARMACEUTICAL TRADEMARKS

David Lossignol
Global Head of Pharma Legal Brand Protection
10.02.2021

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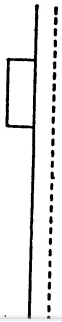
Non Traditional Trademarks ?

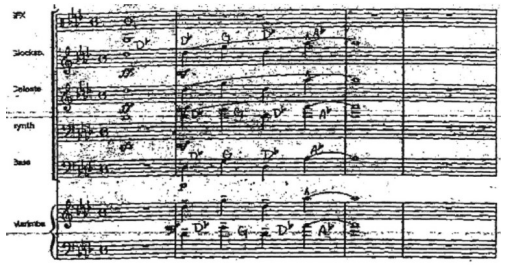
- Definition

- Representation & Description

- Well-Known Examples



The trademark consists of a rectangular label, made of textile, sewn into and protruding from the upper part of the left-hand seam of the rear pocket of trousers, shorts or skirts.



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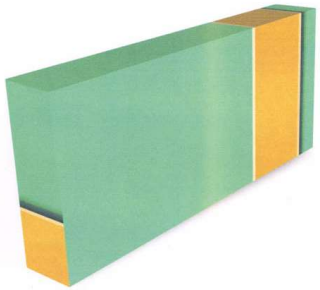
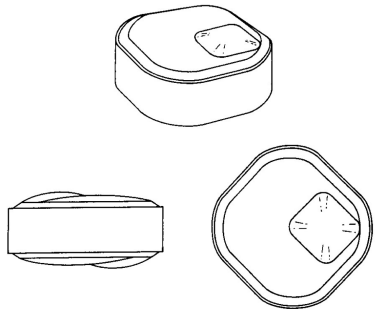
Compatibility between Non-Traditional Trademarks and the Pharma sector ?

- Presumption of functionality ?
- Interests of patients and health care professionals
- Anti-competitive risks ?
- French provisions on IP enforceability & generic oral medicines (Dec 29, 2011)

Non Traditional Pharma Trademarks - Examples





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Main validity threats – distinctiveness and functionality

The following shall not be registered :

- Law on distinctiveness (Art 7(1)(b) EUTMR / Art 3(1)(b) UK TM Act)

(b) trade marks which are devoid of any distinctive character;

- Law on functionality (Art 7(1)(e) EUTMR / Art 3(2) UK TM Act)

(e) signs which consist exclusively of:

(i) the shape, or another characteristic, which results from the nature of the goods themselves;

(ii) the shape, or another characteristic, of goods which is necessary to obtain a technical result;

(iii) the shape, or another characteristic, which gives substantial value to the goods;

Main validity threats – functionality

1. Case-Law on functionality (some non Pharma decisions at a glance)

   – Philips Vs Remington (C-299/99) - prevention of monopoly on technical solutions likely to be sought in the products of competitors + irrelevance of other shapes allowing same technical result

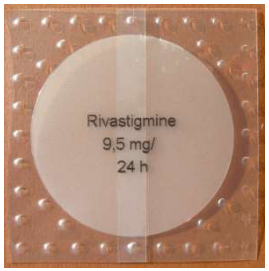
   – Lego (C-48/09) – undertakings may not use TM law in order to perpetuate, indefinitely, exclusive rights relating to technical solutions

   – Kit Kat (C-215/14) – the prohibition does not apply to the manner in which the goods are manufactured

   – PI Design / Yoshida (C-421/15) – all essential elements perform a technical result => no registration despite existence of some non-essential ornamental aspects

Main validity threats – functionality

1. Key EU Pharma Trademark cases on functionality – Exelon Patch of Novartis



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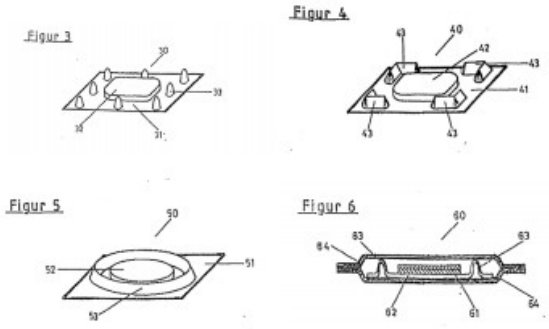
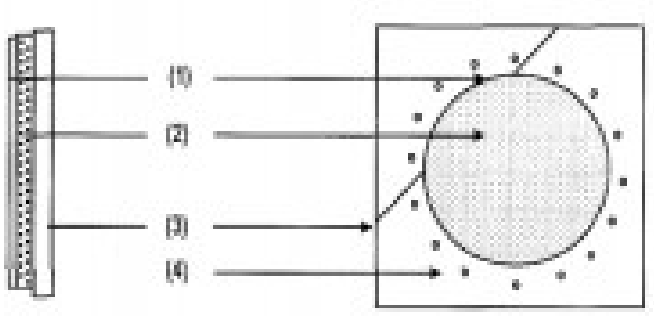
Main validity threats – functionality

1. Key EU Pharma Trademark case on functionality – Exelon Patch of Novartis – Art 7(1)(e)(ii)

Case T44-16





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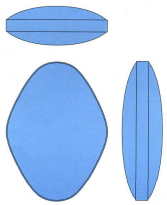
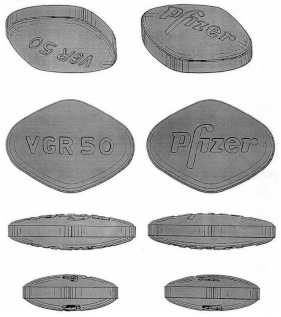
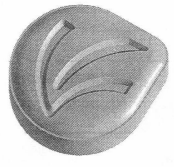
Main validity threats – distinctiveness

1. Some examples







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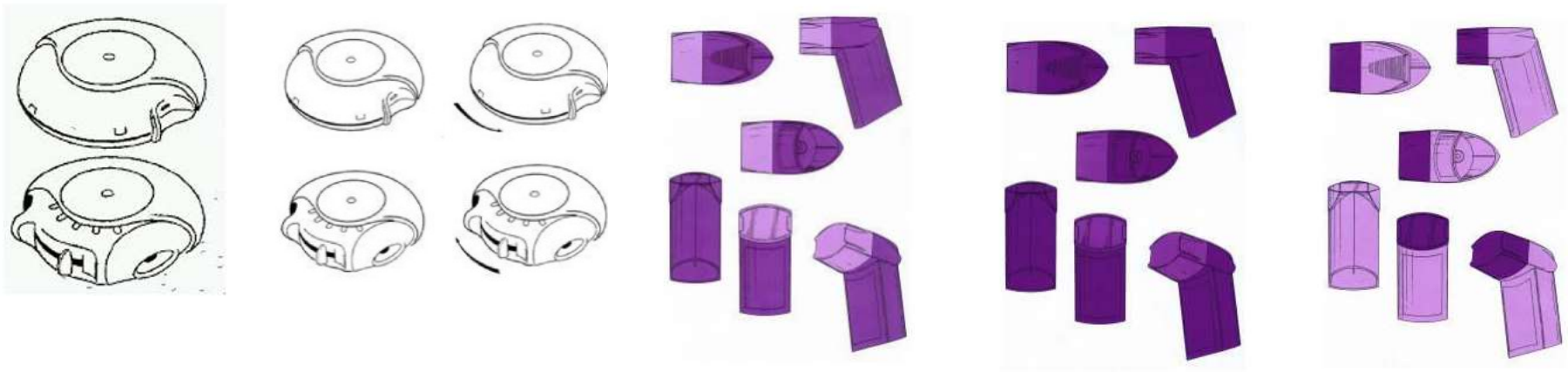
Main validity threats – distinctiveness

1. Some Trademark cases on distinctiveness – 3D marks



Main validity threats – distinctiveness

Glaxo Wellcome UK Ltd (t/a Allen & Hanburys) & Anor v Sandoz Ltd [2017] EWCA Civ 335 (10 May 2017)

The trade mark consists of the colour dark purple (Pantone code 2587C) applied to a significant proportion of an inhaler, and the colour light purple (Pantone code 2567C) applied to the remainder of the inhaler

Case T187-19

Purple (“Pantone code : 2587C”)

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Distinctiveness & Scope of Protection

1. Does this device (left) fall within the scope of protection of these trademarks ?

Distinctiveness & Scope of Protection

1. Does this pill (left) falls within the scope of protection of those trademarks ?

THE PURPLE PILL

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THANK YOU !

Pharmaceutical trade mark confusion and the relevant consumer: Some case law considerations

Gordon Humphreys
Chairperson of the EUIPO First Board of Appeal
Virtual Event, ‘Perfecting Pharmaceutical Trade Mark Protection: Pinnacles and Pitfalls’, 10 February 2021

Relative grounds for refusal – Article 8(1) (b) EUTMR

Article 8(1)(b) EUTMR – Likelihood of confusion

…the trade mark applied for shall not be registered

(b) if because of its **identity** with, or **similarity** to, the **earlier trade mark** and the identity or similarity of the **goods or services** covered by the trade marks 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

Relative grounds of refusal - Article 8(1) (b) EUTMR

Likelihood of confusion (LoC)

- To be assessed **globally** taken into account all relevant factors
- Based on the degree of similarity of the **G&S** and the **overall impression** given by the **marks** (visual, phonetic and conceptual) from the perspective of the relevant public
- Taking into account the **distinctiveness** of the **earlier mark**
- **Interdependence** principle: the more distinctive the earlier mark the more likely is the likelihood of confusion

C-251/95, Sabèl / Puma, §§ 22 - 24

Relative grounds of refusal - Article 8(1) (b) EUTMR – The relevant public

In the global assessment of the likelihood of confusion, account should be taken of the **average consumer** of the category of goods concerned, who is **reasonably well informed and reasonably observant and circumspect**. It should also be borne in mind that the average consumer‘s level of attention is likely to vary according to the category of goods or services in question

T-256/04, Respicur, § 42

Relative grounds of refusal - Article 8(1) (b) EUTMR – The relevant Territory

Article 8(1)(b) EUTMR

.. . if there exists a likelihood of confusion on the part of the public **in the territory in which the earlier mark is protected**

Relative grounds of refusal – Article 8 (1) (b) EUTMR – Similarity between goods and services (G+S)

Factors to be taken into account in assessing similarity:

- Nature
- Intended purpose
- Method of use
- Competition or complementarity

C-39/97, *Canon*, § 17

- Distribution channels of the goods concerned (T-164/03, *Ampafrance* v *OHIM — Johnson & Johnson (monBeBé)* [2005] ECR II-1401, § 53)

WHAT FACTORS ARE TO BE CONSIDERED AND WHEN?

04/03/2020, C-328/18 P, *Black Label by Equivalenza*

- **Faint similarity** between signs is **enough** to trigger the need for a **global assessment** that factors-in criteria such as reputation or recognition of the earlier mark into the LoC equation [§ 60]
- The **circumstances** under which trademarked goods are **marketed** "are to be taken into account at the stage of the **global assessment** of the likelihood of confusion and not at that of the assessment of the similarity of the signs at issue" [§ 70];
- **Counteraction** of **visual and phonetic similarities** can only occur where "at least one of the signs at issue has, from the perspective of the relevant public, a **clear and specific meaning** which can be grasped immediately by that public" [§ 75] – T-441/16, *Sebotherm/SeboCalm*
- Instances of **counteraction** are limited to the **"exceptional case"** [§ 75]. - 17/09/20, C-449/18 P, *Messi/Massi*

WHAT FACTORS ARE TO BE CONSIDERED AND WHEN?

- The **circumstances** under which trademarked goods are **marketed** "are to be taken into account at the stage of the **global assessment** of the likelihood of confusion and not at that of the assessment of the similarity of the signs at issue" [par. 70];
- **Counteraction** of **visual and phonetic similarities** can only occur where "at least one of the signs at issue has, from the perspective of the relevant public, a **clear and specific meaning** which can be grasped immediately by that public" [par. 75]; and
- Instances of **counteraction** are limited to the "**exceptional case**" [par. 75].

Comparison of goods: Therapeutic indications

20/01/21, T-261/19, Mar (DE)**/** OptiMar®

- **BoA** found **'medicated nasal sprays' (PoU) similar or identical** to the 'pharmaceuticals; medicinal sprays; antibacterial sprays; anti-inflammatory sprays; collyrium; ophthalmologic preparations' (Cl. 5) and the 'medical apparatus and instruments' (Cl. 10) BUT not **'medicated dental rinses'**
- **GC held:**
  - **medicated nasal sprays and medicated dental rinses similar to a low degree**
  - **The purposes of these goods are similar: treating the respiratory system**

Cf. 28/05/2020, T-724/18 & T-184/19**, *AUREA BIOLABS (fig.) / Aurea et al.*, § 75**

Comparison of signs: Weakly distinctive elements

20/01/21, T-261/19, Mar (DE)/ OptiMar®

BoA found **no LoC**, despite conceptual similarity and a low degree of visual and phonetic similarity, because earlier mark weak and the relevant public's attention high

GC upheld contested decision:

- **German** public understands **'mar'** refers to the **sea** and it is **well known** that nasal sprays are mainly manufactured from salt water or sea water (para. 41)
- ® **symbol** is **negligible** in the overall impression and the **figurative elements** of the **EUTMA** are **'relatively simple'.**
- **Opti** is either **laudatory** or refers to the **eye**
- The relevant public's level of **attention** is **high**

Goods versus services: Complementarity

25/11/2020, T-802/19, KISS et al. /

EUTMA

KISS COLOR

for pharmaceuticals; sanitary products for medical use, dietetic preparations adapted for medical use, disinfectants (Cl. 5) and cosmetic services, hygienic and beauty care for human beings (Cl. 44)

Earlier TM: sterile implantable products for filling wrinkles, fine lines, cutaneous depressions and for adding volume to the lips in Class 5.

GC upheld contested decision:

- **Relevant public: beauty sector pros (Cl. 5) & gen. pub. of EU (Cl. 44)**
- **Attention level: average to above average (health and beauty)**

Goods versus services: Complementarity

GC's findings (cont'd):

- **Average similarity** between 'Cosmetic services, hygienic and beauty care for human beings' (cl. 44) and 'sterile implantable products for filling wrinkles, fine lines, cutaneous depressions and for adding volume to the lips' (Cl. 5) due **to complementarity**
- **'Certain impression of similarity'** in the mind of the relevant public because the **sole component** of the **earlier mark** entirely is **reproduced in** the EUTMA
- Normal degree of distinctive character of the earlier trade mark

=> LoC

Limits to Complementarity

EUTM application	Earlier trade mark
	APIRETAL

05/10/2020, T 51/19, apiheal (fig.) / APIRETAL

GC's findings:

- 'Perfumery; cosmetics; fragrances; deodorants for personal use and animals; soaps; bath herbs, not for medical purposes' (Class 3) are dissimilar to the opponent's 'antipyretics' (Class 5).
- Although these products are sometimes used together, they are not complementary since one is not indispensable or important for the use of the other and they can be used independently from each other (§ 48).

=> No LoC

THANK YOU FOR YOUR ATTENTION!

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