

Trade dress protection for pharmaceutical packaging

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PTMG 105th Conference – Edinburgh

An in-house perspective

Life forward

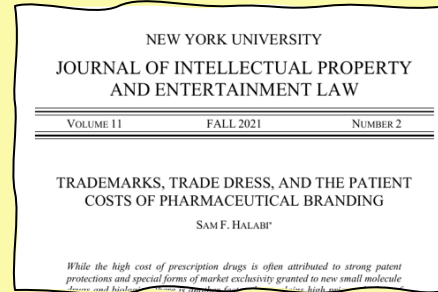
Where to start?

Ask ChatGPT?

Google?



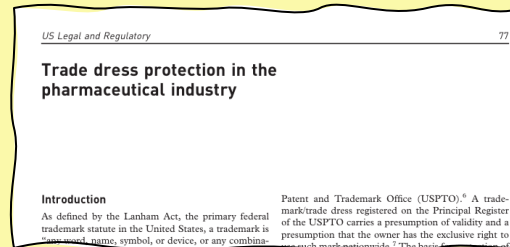
When Google is not of help ...



01

Journal of Generic Medicines
2019, page 76

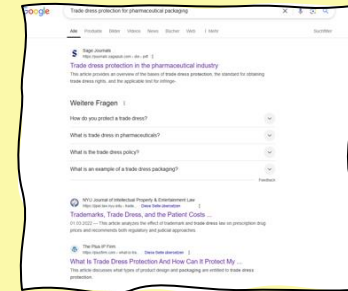
Is about the trade dress protection of the medicinal product itself, not its packaging



02

Journal of Intellectual Property and Entertainment Law (Volume 11, 2021)

Analyzes the cost of pharmaceutical branding; focus on protection of appearance of the medicinal product



03

Article from India
Deals with color trade marks

Let's approach the topic systematically:

What is trade dress?



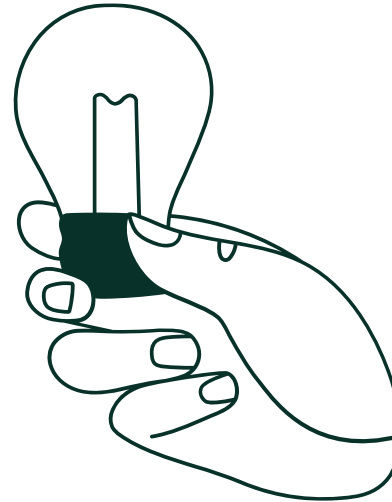
What is trade dress?

DE

Usually referred to as “Aufmachung” (get up); No legal definition; Widely used in several laws (incl. Trademarks Act, law on tobacco products ordinance on wine)

EU

Similar to the situation in DE



Wikipedia

“The characteristics of the visual appearance of a product or its packaging ... that **signify the source of the product** to consumers”

https://en.wikipedia.org/wiki/Trade_dress#United_Kingdom

Appearance is the summary of the design, shape, colour.

Basically, everything that leaves an impression.

Let's approach the topic systematically:

What is pharmaceutical packaging?



What is pharmaceutical packaging?

**DIRECTIVE 2001/83/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 6 November 2001
on the Community code relating to medicinal products for human use
(OJ L 311, 28.11.2001, p. 67)**



Article 1 No. 23 – immediate packaging

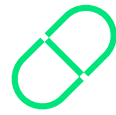
Container or other form of packaging immediately in contact with the medicinal product



Article 1 No. 24 – outer packaging

The packaging into which is placed the immediate packaging

The range of different packaging seems to be limited



Solids

Bottle

Blister



Liquids

Bottle

Syringe

Ampule

Inhaler & Spray

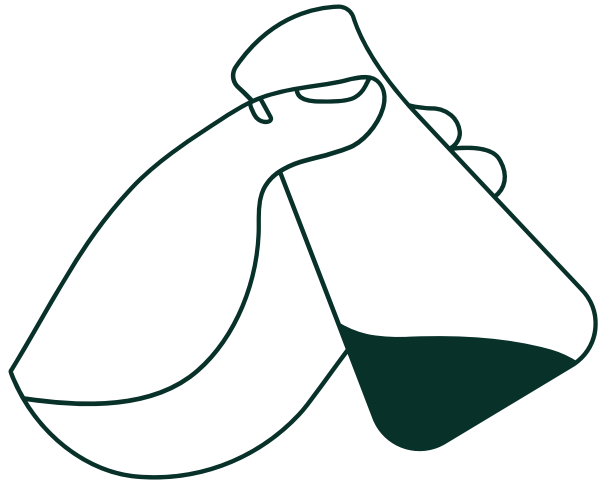
(Injector, incl. pen)



Outer packaging

Folding box / carton

The range of different packaging seems to be limited



**While there are some
interestingly designed inhalers**

...

... these are not packaging

(because the medicinal
product is in a blister)



Impressions from the museum



It seems like things haven't really changed a lot ...

... since the earlier days



Impressions from the museum



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Impressions from the museum



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Impressions from the museum



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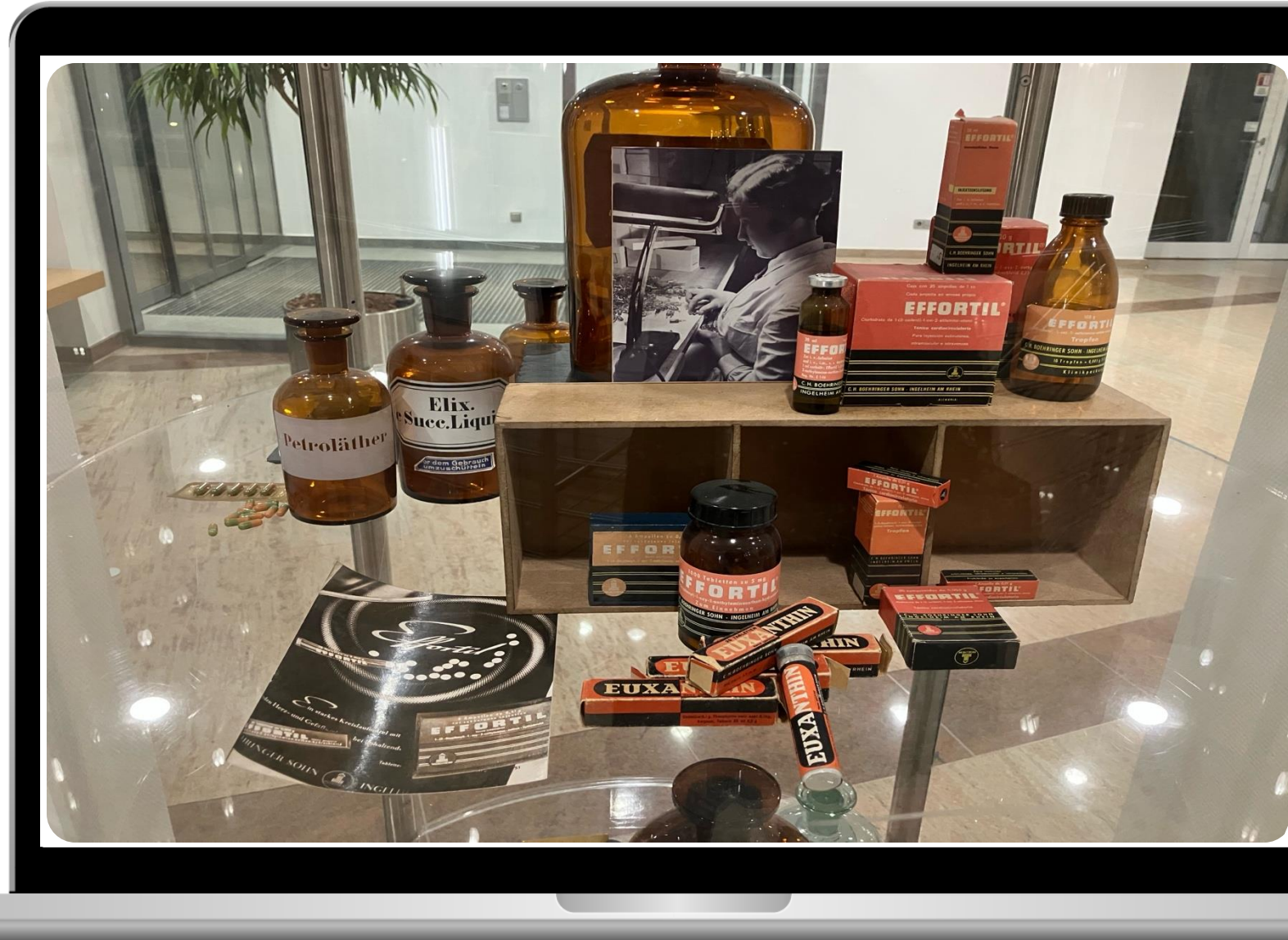


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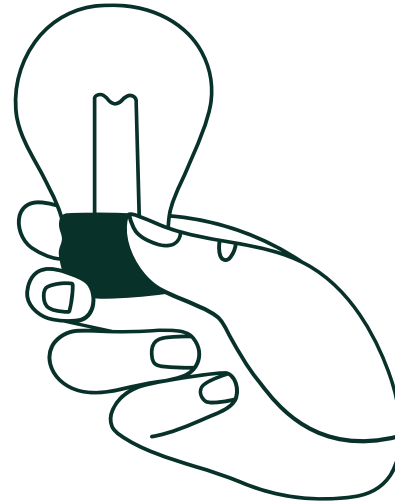
What kind of protection?

Trademark

Get up must be **inherently distinctive** and capable of serving as an **indicator of origin**.

Copyright

Get up must be an **artistic work**, must be **original** and there must be an **author**.



Design

Get up must be **new** and have **individual character**.

Passing off...

... or unfair competition:

Requires some **unfair exploitation of reputation** / protecting the **goodwill** against **misrepresentation**.



All routes of protection require either distinctiveness or individuality or originality or a certain fame (which again requires a certain distinctiveness).

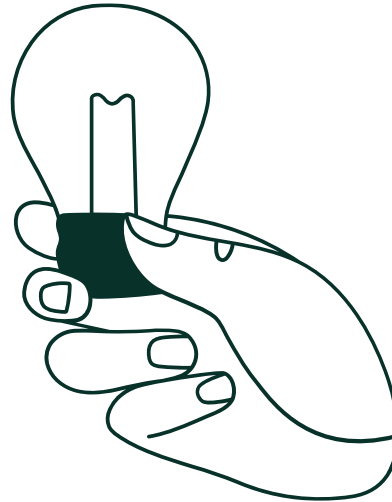
Hurdle: functionality

Trademark

Article 7, 1.(e)(ii) EUTM Regulation:

Signs which consist exclusively of the shape of goods necessary to obtain a technical result shall not be registered.

But functionality and safety are obviously critical to pharmaceutical packaging. Processes are widely standardized.



Design

Article 8, 1. Community Design Regulation:

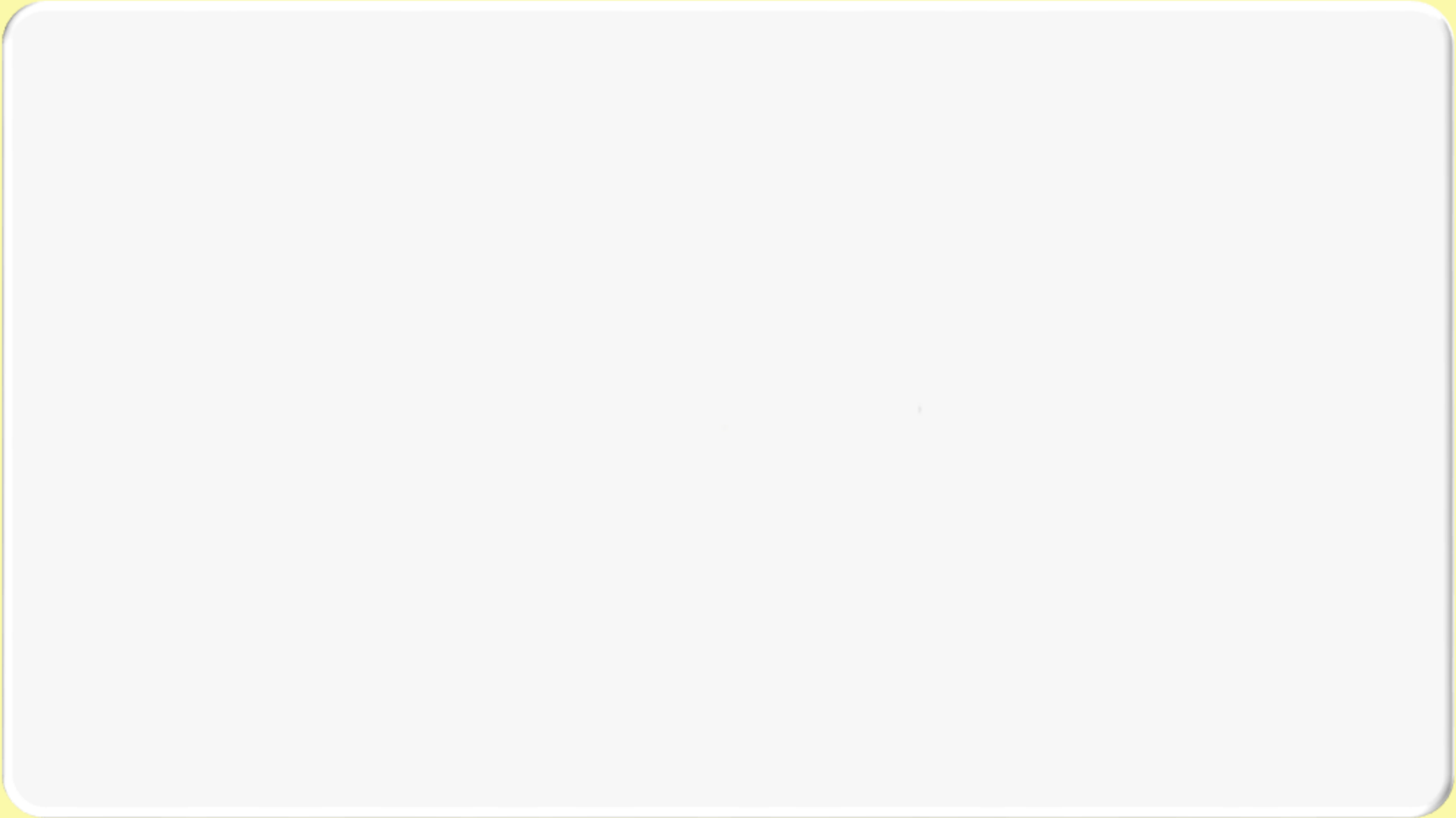
A design shall not subsist in features of appearance of a product which are solely dictated by its technical function.

The shape of a packaging doesn't really seem to be of importance for this very specific kind of products.

Back to the in-house perspective:

TWISTPAK is an innovative packaging with certain distinctiveness:



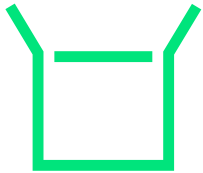


Solution?

Make the concept a brand: TWISTPAK



Some views on outer packaging

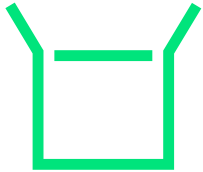


For decades,

Boehringer Ingelheim has been using a pack design which we refer to as “Tricolore”.

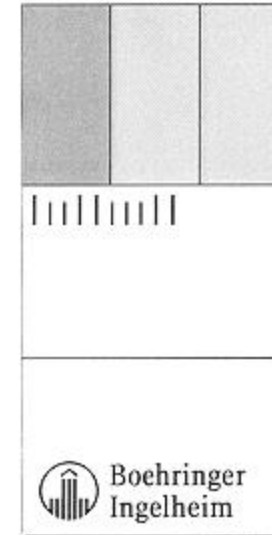


Some views on outer packaging



The “Tricolore” is unique, distinct and a well-known indicator for the source of origin ...

... but it is not static.



And this is how the trademark registration looks like.

Challenges



Art 54 Directive 2001/83 (community code relating to medicinal products for human use):

“The following particulars shall appear on the outer packaging of medicinal products or, where there is no outer packaging, on the immediate packaging:”

Art 56 Directive 2001 / 83:

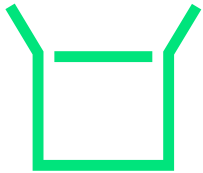
„The particulars ... shall be easily legible, clearly comprehensible and indelible.“

- Name, followed by strength and pharmaceutical form
- International Nonproprietary Name
- statement of the active substances expressed qualitatively and quantitatively per dosage unit
- pharmaceutical form and the contents by weight, by volume or by number of doses
- method of administration
- Special warnings and storage conditions
- Name and address of MA holder
- Batch number and MA number ...



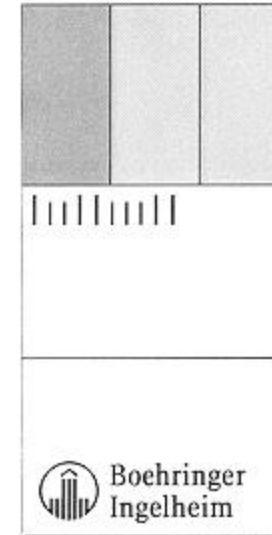
Just an excerpt!

Some views on outer packaging



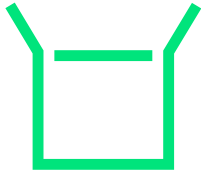
Obviously, the outer packaging for medicinal products has an important function:

Provision of information



Distinctive features of the packaging are considered to space consuming...

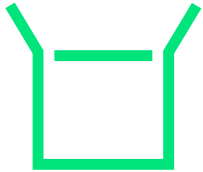
Some views on outer packaging



New “Tricolore”:

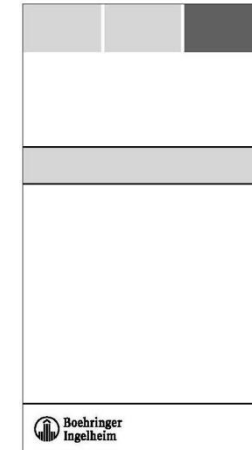
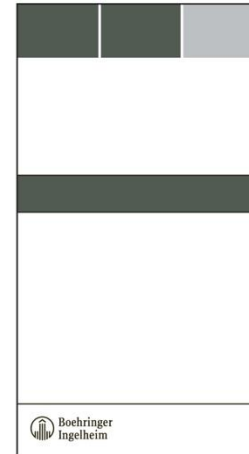
- Identifying product & strength
- Dosage strength bar
- Divider & company logo

Some views on outer packaging



New “Tricolore”:

- Identifying product & strength
- Dosage strength bar
- Divider & company logo



And this is how the trademark registration looks like

Some views on outer packaging



The new “Tricolore” ...

... contributes to product safety by differentiation and helps to avoid medication errors.



Remember how a drawer or shelf in a pharmacy looks like.

Photo source: Cajón de medicamentos para la venta en Farmacia – Samuel – stock.adobe.com

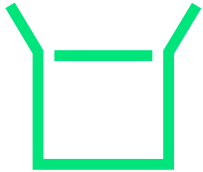
The challenge...

... for trademark protection and registration is to overcome the hurdle of distinctiveness.

But do such trade dress concepts qualify for copyright protection?

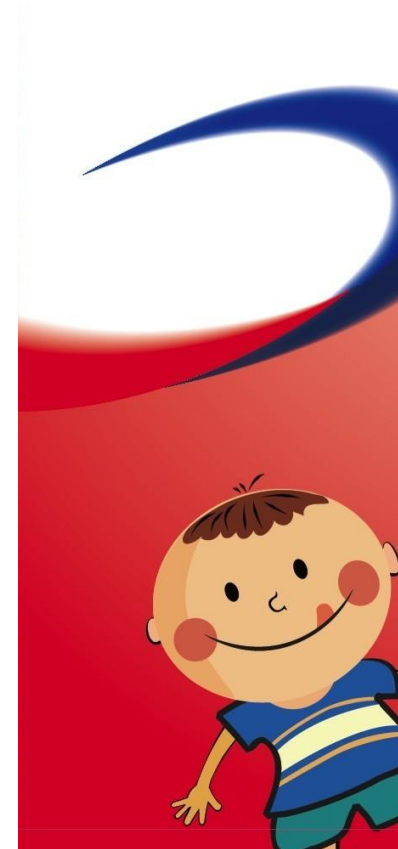


Copyright



Potential copyright protection ...

... obviously depends on the case.



registered copyright in CN

Final thoughts

The tension is obvious:

- Clear information
- Differentiation
- Promotional aspects



Challenges

Some legislations may well lead to indistinctiveness.

... and remind a bit of plain tobacco packaging

Photo source: Edson Souza - stock.adobe.com



