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PHARMACEUTICAL TRADE DRESS ISSUES IN BRAZIL

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Pharmaceutical trade dress issues in Brazil

Topics to be covered:

- (1) Legal framework
- (2) Requirements for trade dress protection
- (3) Recent case law: *Edwards v. Meril*
- (4) The importance of expert evidence
- (5) Registration of trade dress as a trademark
- (6) Key takeaways

(1) Legal framework

Brazilian statutory law does not provide a definition of trade dress.

The Superior Court of Justice filled the gap:

“ Trade dress is the overall visual appearance of an object, a product or its packaging. It is the distinctive manner in which it is presented and becomes known.

JUSTICE LUIS FELIPE SALOMÃO

Superior Court of Justice, Special Appeal No. 1,306,690/SP · 4th Panel · Apr. 10, 2012

“ Trade dress is the combination of visual and sensory elements that results in a unique and sufficiently distinctive form of presenting a product to consumers.

JUSTICE MARCO AURÉLIO BELLIZZE

Superior Court of Justice, Special Appeal No. 1,353,451/MG · 3rd Panel · Sept. 19, 2017

Brazilian case law recognizes the source-identifying function of trade dress and has progressively expanded the scope of the doctrine.

(1) Legal framework

Legal provisions providing protection:

Brazilian Constitution:

The law shall guarantee protection of trademarks, company names and **other distinctive signs**, taking into account the social interest and the technological and economic development of the Country.

Industrial Property Act / Unfair Competition rules:

Unfair competition is committed by anyone who employs **fraudulent means to divert another party's clientele** for their own benefit.

The injured party shall be entitled to recover damages for (...) **acts of unfair competition** intended to: (i) harm another party's reputation or business; (ii) **create confusion between commercial establishments or service providers**, or (iii) **create confusion between products and services placed on the market**.

(2) Requirements for trade dress protection

Three requirements to prevail in a trade dress dispute:

- (i) Distinctiveness;
- (ii) Likelihood of confusion; and
- (iii) Non-functionality.

(2) Requirements for trade dress protection

1st Requirement: Distinctiveness

- To be protectable, trade dress must distinguish the product or service from similar products or services originating from different sources.
- Trade dress may be inherently distinctive or may acquire distinctiveness through use.

(2) Requirements for trade dress protection

1st Requirement: Distinctiveness



(2) Requirements for trade dress protection

1st Requirement: Distinctiveness



(2) Requirements for trade dress protection

1st Requirement: Distinctiveness



*“The Defendant’s product imitates the shape, appearance and, in particular, **the distinctive green and yellow colors** that have been incorporated into the Plaintiff’s product for many decades.”*

Hypera vs. Pharmascience, São Paulo Court of Appeals, Appeal nº 1062421-73.2018.8.26.0100,, 2nd Corporate Chamber, Reporting Judge: Ricardo Negrão, May 4, 2021

(2) Requirements for trade dress protection

1st Requirement: Distinctiveness



“ The elements in question are diluted within the intimate-care soap market, so the Appellee cannot claim exclusive rights over such “visual codes” that are characteristic of this market segment.

These types of trade dress may be considered “category codes” that are common and expected for intimate-care soaps in the Brazilian market, which may reduce their distinctiveness and make them “weak” in the absence of other innovative or exclusive elements.

Sanofi Medley vs. Healthy do Brasil, São Paulo Court of Appeals, Appeal nº 1028013-51.2021.8.26.0100, 2nd Corporate Chamber, Reporting Judge: Grava Brazil, December 16, 2025

(2) Requirements for trade dress protection

2nd Requirement: Likelihood of confusion

- To prevail, the Plaintiff must establish a likelihood of confusion between the products.
- The analysis should focus on the overall impression, rather than on isolated elements.
- Evidence of actual confusion is not required.
- Case law addresses not only traditional passing off situations, but also deceptive association and free riding on the goodwill associated with the Plaintiff's product.

(2) Requirements for trade dress protection

2nd Requirement: Likelihood of confusion



“The similarity in the overall trade dress of the Plaintiff’s product and the Defendants’ product, **particularly the distinctive combination of colors, lettering arrangement, and geometric and graphic elements, indicates a likelihood of consumer confusion.**”

Hypermarcas vs. Cimed, São Paulo Court of Appeals, Appeal nº 1124478-64.2017.8.26.0100, 1st Corporate Chamber, Reporting Judge: Pereira Calças, June 5, 2020

(2) Requirements for trade dress protection

2nd Requirement: Likelihood of confusion



“Evidence of actual confusion between the products or services is not required: likelihood of confusion is sufficient.

“The parties’ products share a number of visual features, including a cylindrical, transparent vial; a circular yellow cap and yellow liquid; blue lettering displayed vertically in an ascending direction; and the common suffix ‘-CLER’.

“In light of these similarities in the products’ overall appearance, the likelihood of consumers confusing EPOCLER with BENECLER cannot be disregarded, potentially leading them to purchase one product in the mistaken belief that they are purchasing the other.”

Hypermarcas vs. Brasterápica, São Paulo Court of Appeals, Appeal nº 1089875-67.2014.8.26.0100, 2nd Corporate Chamber, Reporting Judge: Sérgio Shimura, December 15, 2020

(2) Requirements for trade dress protection

2nd Requirement: Likelihood of confusion



“Even to the untrained eye, it is clear that the trade dresses of the two products are distinct, with different arrangements of elements and illustrative images.

The packaging of the products are sufficiently distinct, **with no likelihood of consumers being misled by their visual appearances .”**

Farmoquimica v. Natulab, Rio de Janeiro Court of Appeals, Appeal nº 0255819-71.2016.8.19.0001, 21st Corporate Chamber, Reporting Judge: Pedro Raguene, September 21, 2021

(2) Requirements for trade dress protection

3rd Requirement: Non-functionality

- Features dictated by a practical or functional purpose generally cannot serve as indicators of source:

TABLET COLOR



Color may identify dosage rather than source

TABLET SCORING



The score line enables tablet splitting

PACKAGING



Configuration may protect the pills and organize unit doses

DELIVERY DEVICE



Configuration may be dictated by administration mechanics

(2) Requirements for trade dress protection

3rd Requirement: Non-functionality

- Important Brazilian precedent on trade dress functionality:

“

The elements comprising the trade dress must not serve any function or purpose other than specifically distinguishing the product in the relevant market.

In other words, where the graphic and visual features are arranged in a particular manner due to requirements inherent to the technical or primary functionality of the product or service, they are not afforded trade dress protection”.

Superior Court of Justice, Special Appeal No. 1,843,339/SP, 3rd Panel, Reporting Judge Nancy Andrighi, December 3, 2019

(3) Recent case law: Edwards v. Meril

Case: Edwards v. Meril, São Paulo Court of Appeals, July 29, 2026.

Discussion: Can the appearance of a highly technical medical device be protected as trade dress?



SAPIEN 3 - EDWARDS

vs.



MYVAL - MERIL

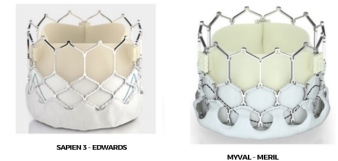
Edwards alleged that Myval unlawfully imitated the trade dress of Sapien 3.

(3) Recent case law: Edwards v. Meril case

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Some additional context:

- Edward's Sapien 3 is a market-leading transcatheter heart valve in Brazil.
- Myval was launched on the market at a price approximately 40% below that of Sapien 3.
- Both products were registered with the Brazilian Health Regulatory Agency (ANVISA).
- Meril also relied on clinical studies conducted by Edwards to promote the safety and efficacy of Myval.
- Other competing transcatheter valves were available in the Brazilian market:



(3) Recent case law: Edwards v. Meril

Key legal issues:

1

FUNCTIONALITY

Were the similarities dictated by technical or clinical requirements?

2

DISTINCTIVENESS

Did SAPIEN 3's overall appearance function as an indicator of source?

3

CONFUSION / ASSOCIATION

Could the similarity create confusion or at least an association between the products?

4

RELEVANT CONSUMER

Cardiologists only? Or also hospital procurement departments, health insurance companies and other decision-makers?

(3) Recent case law: Edwards v. Meril



Majority opinion: no protectable trade dress.

Functionality	Principal similarities were dictated by technical and clinical requirements .
Limits of the doctrine	Trade dress cannot provide indefinite exclusivity over functional product features.
Specialized market	Transcatheter valves are selected and purchased in a highly specialized clinical environment .
Relevant consumer	The majority emphasized technical expertise and the high degree of care exercised by the professionals involved.
Confusion	In that context, the similarities were insufficient to create a likelihood of confusion .



FUNCTIONALITY + SOPHISTICATED CONSUMER → NO ACTIONABLE CONFUSION →

**EDWARDS' CLAIM
WAS REJECTED.**

(3) Recent case law: Edwards v. Meril



Dissenting opinion: functionality requires a more precise inquiry.

Functional features

The dissent agreed that functional features are not protectable. **It disagreed on what makes a feature functional.**

The right question

The right question is **not whether the feature performs a function**, but whether the particular configuration is necessary to perform that function.

Alternative design

INOVARE performed the same essential medical function with a **different configuration**.



SAPIEN 3 - EDWARDS



MYVAL - MERIL



INOVARE

KEY TAKEAWAY
FROM THE DISSENT

A commercially viable alternative design undermines the conclusion that the overall impression of SAPIEN 3's specific configuration was dictated by function.

(3) Recent case law: Edwards v. Meril

Dissenting opinion on distinctiveness and the relevant consumer.

86.6%

of cardiologists surveyed
spontaneously identified
SAPIEN 3 solely by its
overall appearance.



WHO IS THE RELEVANT CONSUMER?

The majority emphasized highly specialized interventional cardiologists and the technical nature of the purchasing decision.

THE DISSENT TOOK A BROADER VIEW:

- **Hospital procurement departments**
- **Health insurance plans/payors**
- **Other professionals involved in the purchasing decisions.**

The relevant public could not necessarily be reduced to the physician who ultimately selects or implants the valve.

(3) Recent case law: Edwards v. Meril

Dissenting opinion on distinctiveness and the relevant consumer.

Even physicians could potentially confuse the valves once implanted in the patient's body: a potential scenario of post-sale confusion.



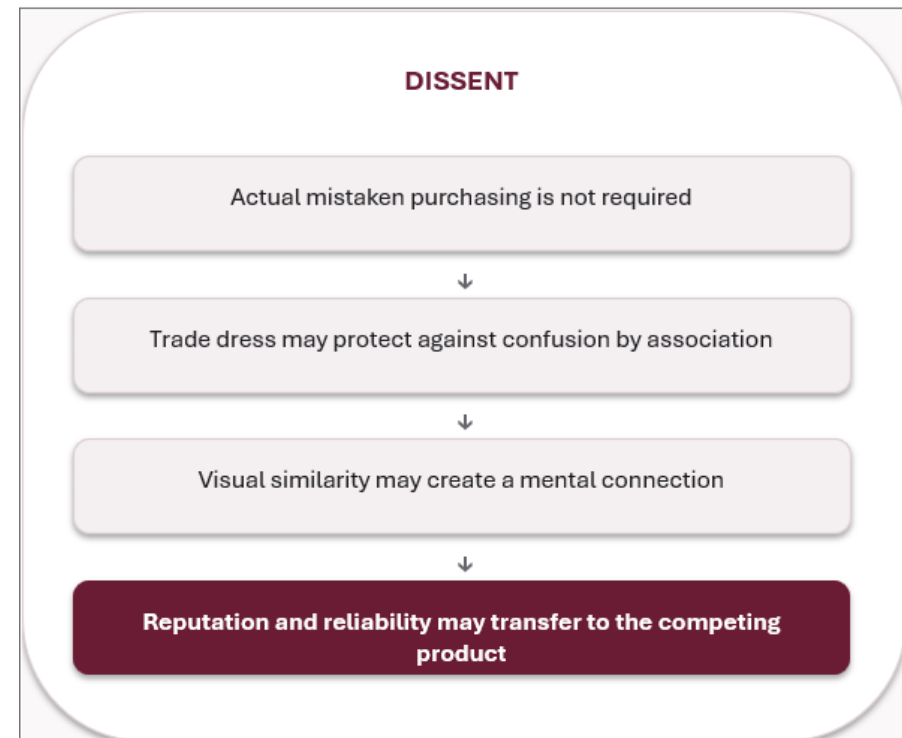
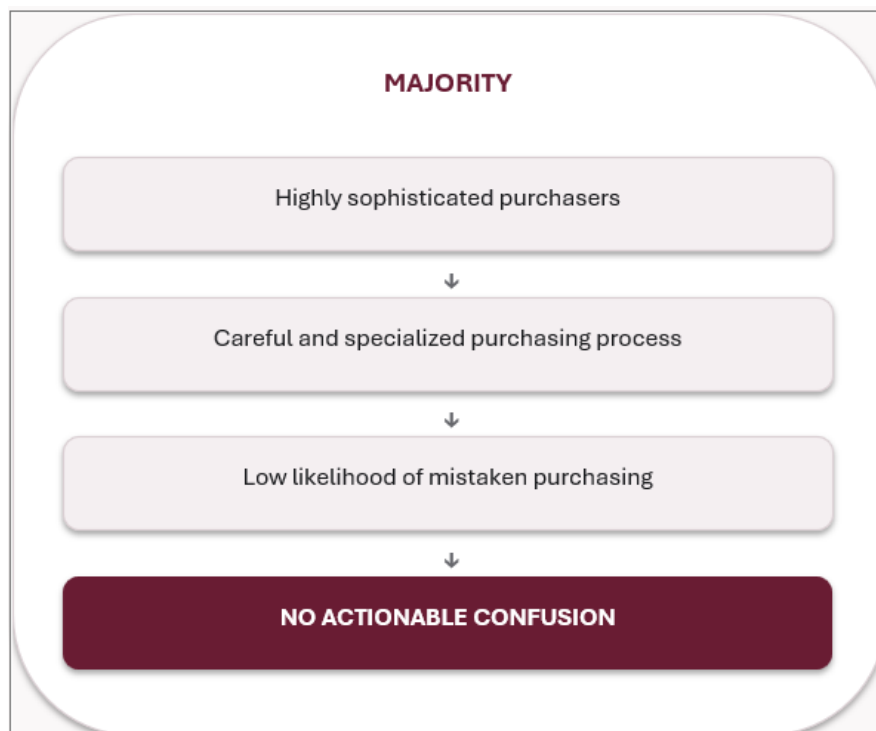
Sapien 3 (Edwards)



MyVal (Meril)

(3) Recent case law: Edwards v. Meril

The divide: Confusion vs. Association



The case is not yet finalized and will probably be decided by the Superior Court of Justice

(4) The importance of expert evidence

In Brazil, the expert is appointed by the judge, not by the parties.

In a 2019 decision, the Superior Court of Justice decided that trade dress is a complex issue and that its assessment requires expert evidence:

“Trade dress is complex and consists of a combination of multiple elements. Given the absence of specific statutory regulation and the fact that trade dress is not subject to registration, whether imitation has occurred and whether it amounts to unfair competition must be determined on a case-by-case basis.

For this purpose, expert evidence is essential in assessing factors such as (i) market conditions, (ii) consumer habits, (iii) advertising and marketing practices, (iv) the degree of attention exercised by the ordinary consumer of the product concerned, (iv) the time at which the product was introduced into the market, as well as other elements that confer identity to the particular trade dress.”

JUSTICE MARIA ISABEL GALLOTTI

Brazilian Superior Court of Justice (STJ), Ritter v. Queensberry, Special Appeal No. 1,778,910/SP, 2019.

(4) The importance of expert evidence

Practical impact of the Superior Court of Justice's precedent:

- Following this precedent, trial courts are increasingly deferring rulings on preliminary injunction requests until expert evidence becomes available.
- Other courts are ordering expert evidence at an early stage, before ruling on preliminary injunction requests.
- Court-appointed experts now play a critical role in trade dress disputes.
- It is therefore essential to provide the expert with robust supporting evidence, including documents, consumer surveys and market studies.

(4) The importance of expert evidence

SÃO PAULO COURTS



- Trial Court: PI **rejected**
- Appeal Court : **rejection upheld**

- Trial Court: **PI granted**
- Appeal Court : **overturned**

RIO DE JANEIRO COURTS



- Trial Court: PI **rejected**
- Appeal Court : PI **granted**

- Trial Court: **PI granted**
- Appeal Court : **overturned**



- Trial Court: **PI granted**
- Appeal Court : **PI upheld**

(4) The importance of expert evidence

Are courts placing too much weight on expert opinions in trade dress cases?

(5) Registration of trade dress as a trademark

It is possible to register a trade dress as a trademark in Brazil.

Main advantages of the registration:

- Prima facie evidence that the trade dress is distinctive.
- Acquisition of proprietary rights.
- Nationwide rights.
- Greater likelihood of obtaining preliminary injunctive relief.

(5) Registration of trade dress as a trademark

3D TRADEMARKS

Shapes that were registered in Brazil:



Reg. No. 911091963



Reg. No. 919040454



Reg. No. 908652593



Reg. No. 829278095



(5) Registration of trade dress as a trademark

2D WORD AND DESIGN MARKS

Marks that are registered in Brazil:



Reg. No. 936335912



Reg. No. 919555470



Reg. No. 928575802



Reg. No. 910367825



PENDING APPLICATIONS



No. 936308885



No. 936308311

BPTO requested the Applicant to submit a new image of the trademark



Key takeaways

- Brazilian law provides an adequate legal framework for the protection of trade dress.
- Brazil has developed a remarkably sophisticated body of case law on trade dress.
- Functionality remains one of the key boundaries of trade dress protection.
- The relevant consumer, and the degree of attention exercised by that consumer, may be decisive.
- Expert evidence has become increasingly important in Brazilian trade dress litigation.
- Whenever possible, trade dress owners should consider registration as part of a broader protection strategy.

Thank you!

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