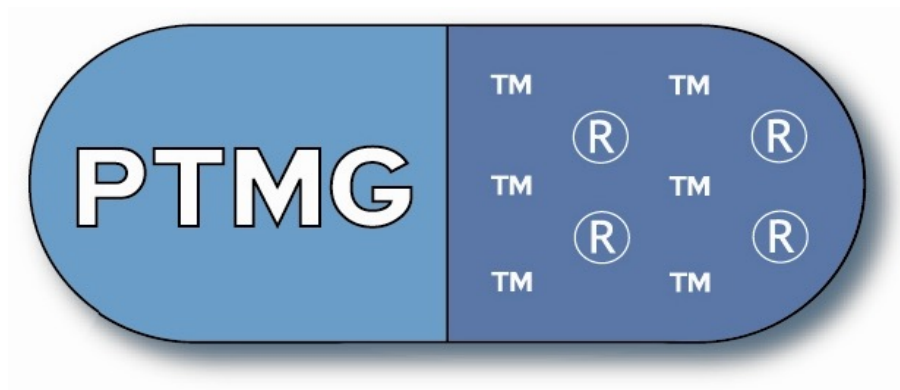
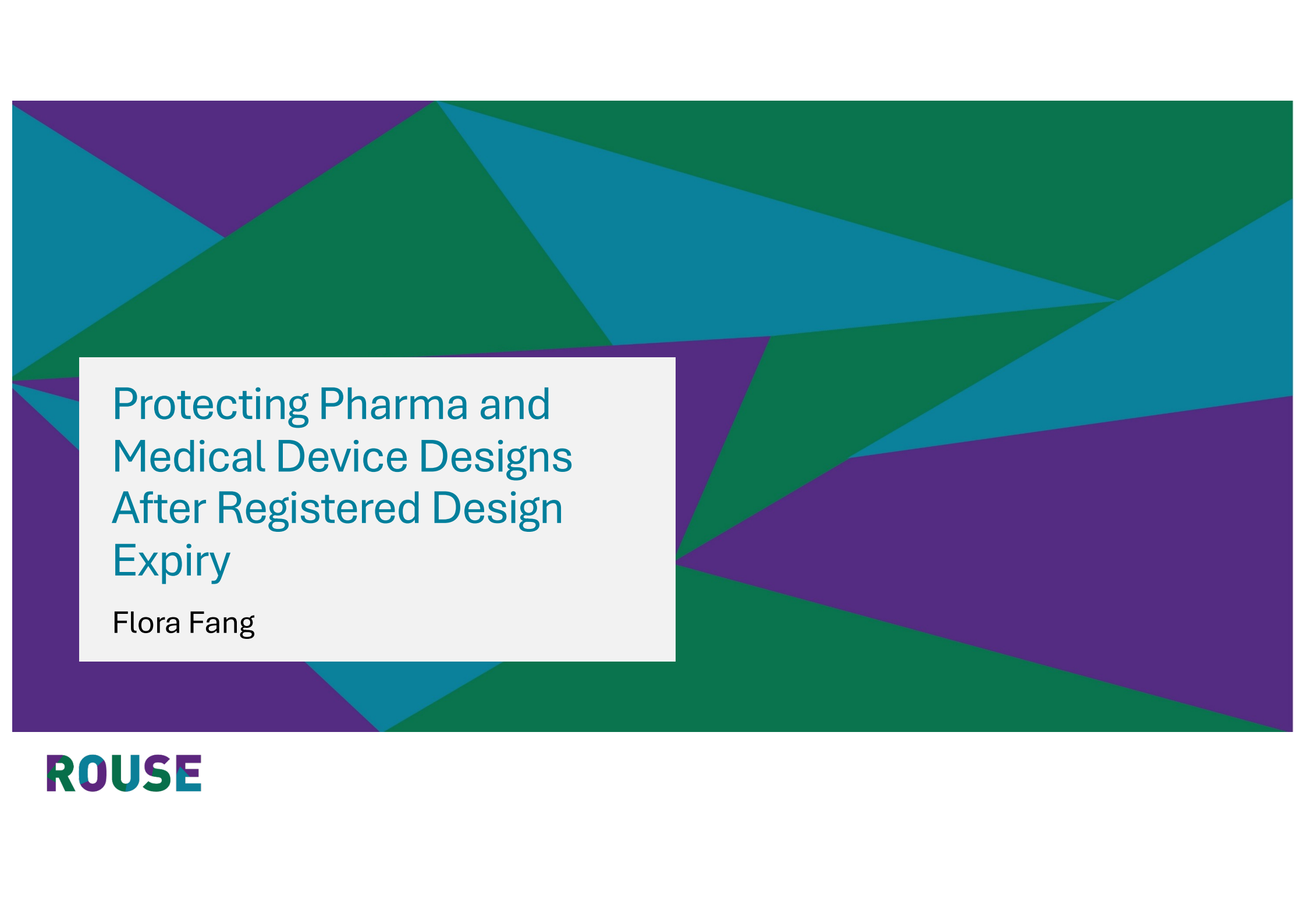




Flora Fang

Rouse



Protecting Pharma and Medical Device Designs After Registered Design Expiry

Flora Fang

ROUSE

The Dual Lifecycle Challenge

Pharmaceuticals and medical devices have two lifecycles:



When a design expires, the right dies, but the product may still be alive - even at the peak of its commercial success.



Today's Roadmap



Available post-design legal pathways in China

1

The position of Chinese courts

2

US / EU / UK comparative Overview

3

Practical strategy and key takeaways

4

Post-design Legal Pathways



Comparison of Four Protection Paths in China

Protection Path	Legal Basis	Term	Key Thresholds	Applicable Scenarios
Design	Patent Law	15 years	Novelty + Distinctiveness	Comprehensive protection for new products
3D Trademark	Trademark Law	Renewable	Distinctiveness + Non-functionality	3D forms (product shapes, packaging, etc.)
Unfair Competition	Anti-Unfair Competition Law	No fixed term	Certain influence + Distinctive features	Trade dress, packaging, etc.
Copyright	Copyright Law	50 years	Originality + Substantial similarity	Packaging patterns, labels, etc.

Deep Dive into Chinese Court Cases



Puzzle Time



How many design patents were granted in China in 2025?

- A About 66,000
- B About 666,000
- C About 1.66 million

Overview of China's Patent Data

Year	Design Grants (IP Statistical Yearbook)	Valid Registrations (Year-End, IP Statistical Yearbook)	Invalidation Decisions (Annual Report)
2021	785,521	2,580,532	2,333
2022	720,907	2,831,512	2,651
2023	637,944	3,233,684	2,895
2024	643,318	3,073,912	3,517
2025	666,245	3,170,825	3,835

3D Trademark: Pfizer Blue Diamond Tablet - Facts & Procedure history

*Core issue: Does a
tablet shape inside
opaque packaging
function as a
trademark at the point
of purchase?*

3D Trademark Infringement



Pfizer VGR blue diamond-shaped tablet
(Reg. No. 3110761, Class 5)



Defendant's product picture

The procedure

First instance → Beijing High Court (reversed) → SPC
retrial (endorsed)

The Facts

- **Pfizer** held a registered 3D trademark for a **blue diamond-shaped tablet** (Class 5).
- **Defendant** (Jiangsu Lianhuan Pharma) produced a **light-blue, near-diamond tablet** marked "Wei Ge" and "TM".
- **First instance:** infringement found, RMB 300K awarded.
- **Beijing High Court (appeal):** reversed. **SPC (retrial):** endorsed the appellate reasoning.

3D Trademark: Pfizer Blue Diamond Tablet - Holding & Key Takeaways

Why the 3D Mark Claim Failed

01 Invisible at point of sale

The tablet is sealed inside opaque blister packaging

02 Source information elsewhere

“Wei Ge”, “TM”, manufacturer name on packaging

03 No trademark-use function

The tablet shape does not identify source in the transaction

Key Lesson

Prove **visibility and recognition** at the point of purchase.

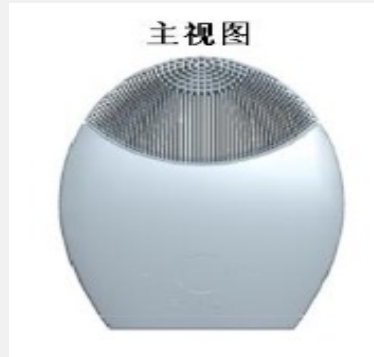
Opaque packaging = **structural barrier** for tablets.

3D marks work better for **external device shapes** - but need acquired distinctiveness evidence

Unfair Competition: Foreo LUNA Cleansing Device - Facts & Result

Article 6 of the Anti-Unfair Competition Law protects packaging and decoration that has acquired "certain influence" in the market - the most actively used successive protection pathway in China for pharmaceutical and health products

Unfair Competition (Trade Dress)



Foreo LUNA series -
overall contour + bristle arrangement

Background - Design Patent Claim Failed First

- **Design patent claim** → failed (no identity or similarity)
↓
- Switched to **Anti-Unfair Competition Law** Art. 6 → LUNA's overall shape + bristle arrangement = influential trade dress

Result - Hangzhou Intermediate Court (2024)

- **No double-counting bar:** design patent and trade dress protect **different legal interests**.
- LUNA's visual combination acquired **stable source association** through long-term sales and promotion.
- **Damages: RMB 1.5M; upheld on appeal.**

Unfair Competition: Betaloc (Metoprolol) Packaging - Facts & Result

Unfair Competition - Pharma Packaging



AstraZeneca - colour scheme + box layout



Defendant - colour scheme + box layout

Facts - Later Design Patent Cannot Defeat Prior Trade Dress

- AstraZeneca's Betaloc packaging - **colour combination, layout, text proportions** - had been in use for years, building **stable brand recognition**.
- Defendant copied the **overall visual impression**, then argued its **later-filed design patent** could defeat the claim.
- Court: **A later patent cannot override prior trade-dress rights.**

Result & Key Principle

- **Constituted unfair competition. Total damages: RMB 5.75M** (RMB 5.5M economic loss + RMB 250K costs).
- **Principle:** A later-filed design patent **cannot override prior trade-dress rights.**

Additional Trade Dress Cases - Brief Overview



VS



VS



Baiyunshan Xiao Chai Hu Granules

OTC Chinese medicine - SUCCEEDED

Early design patent for the box + sachet, then
~30 years of continuous use as trade dress.

Defendant's "Shuanglong Chuhai" packaging
was highly similar in colour, element selection,
and layout.

Court recognized the packaging as **influential
trade dress. Damages: RMB 300,000.**

Takeaway

Early design patent + decades of consistent
use can mature into independent trade-dress
rights.

Additional Trade Dress Cases - Brief Overview



Common principle: Long-term, consistent use of non-functional packaging elements converts design into protectable trade dress - regardless of whether the original design patent is still in force.

999 Cold-Relief Granules

OTC pharmaceutical packaging - SUCCEEDED

Iconic OTC cold medicine packaging with distinctive colour scheme and layout.

Court emphasised that **packaging confusion in pharmaceuticals raises patient-safety risks**, weighing in favour of protection.

Reinforces that OTC drug packaging can qualify as **influential trade dress**.

Takeaway

For OTC drugs, consumer safety is an additional policy factor supporting trade-dress protection.

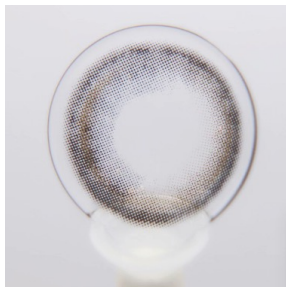
Copyright Protection - Where It Works and Where It Do Not

Copyright protects original artistic expression separable from functional elements.

The key divide:

Functional product designs vs. Packaging graphics

✗ Functional product designs - Rarely Protected



Colored Contact Lens Pattern - copyright failed

Conventional dot-matrix pattern, constrained by function and industry standards → no originality, no copyright.

KEY INSIGHT

Functional product designs require a **higher artistic threshold** - registration alone is not enough.

✓ Packaging Graphic designs - Readily Protected



Doxycycline Capsule Box - copyright succeeded

Unique color palette, arcs, and layout constitute original artistic expression.

KEY INSIGHT

Packaging visuals have a **low originality threshold**. Unique aesthetic choices qualify, making copyright a practical tool for pharma brand defense.

Comparison of IP Protection Pathways for Pharma and Medical Device Designs in China

Design patents as the primary pathway; other IP types offer supplementary protection but with more limited subject matter

Pathway	Best For	Advantages	Key Limitation
Design Patent	New products, packaging, bottle shapes, labels, medical device components.	Registration system – preliminary exam; low cost, relatively stable rights; Broad subject matter	15 years, non-renewable; Must file before launch
3D Trademark	3D forms (product shapes, packaging, etc.)	No term or filing deadline; Enforcement via administrative complaints, platform complaints, customs recordal	Very limited success cases; Non-functionality + distinctiveness hurdles; Registration does not guarantee enforcement
Unfair Competition	Post-expiry succession protection	No term limit; Can continue after design patent expiry or enforcement failure	Higher evidentiary threshold - must prove "influential trade dress" with market, sales, and advertising evidence
Copyright	Packaging graphics, labels, artwork, etc.	50 years – Far longer than design patents; Automatic protection + voluntary registration; Coexist with design patents	Limited scope - packaging graphics are easier to protect; product shapes constrained by function rarely meet the originality threshold

US / EU / UK Comparative Overview



United States: Color Mark and Trade Dress Protection Under the Lanham Act

Distinctiveness

Must possess inherent or acquired "secondary meaning"; the cornerstone of trade dress protection.

Non-Functionality

Traffix doctrine: utility patents are strong evidence of functionality; functional features cannot be protected.

Likelihood of Confusion

Consumer confusion or mistake about product source is the core element of infringement.

SIGNIFICANCE

A rare successful case for pharmaceutical color protection. The core lesson: a color must **transform from an ordinary visual element into a stable source identifier**. It requires decades of consistent use and massive advertising evidence.

CASE

AstraZeneca AB v. Dr. Reddy's Laboratories, Inc.
(D. Del. 2015)

Basis: Color trademark - purple for gastrointestinal drugs (Prilosec & Nexium), "THE PURPLE PILL®"

Evidence: Continuous purple use since 1989; 2.26B+ purple capsules sold; massive advertising across TV, radio, print, and digital media.

Holding: Preliminary injunction granted. Court emphasized long, continuous, concentrated use; advertising investment; market recognition; and FDA's acknowledgment of the "purple pill" - product association.



European Union: Registered Designs & Unregistered Right

EU: Registered Designs as Core, Unregistered as Supplementary

- Registered EU design provides up to 25 years, requiring active application;
- Unregistered design protects only 3 years; protection is confined to identical products - it only allows action against 1:1 copycats
- Strict examination for 3D appearance of pharmaceutical products – **functional exclusion** applies

SIGNIFICANCE

EU authorities and courts apply **strict scrutiny to color and 3D shape marks in the pharmaceutical sector**, requiring proof that the relevant public perceives the feature as a source identifier rather than a product or functional attribute. However, in health and consumer product sectors, packaging trade dress that has acquired market recognition through continuous use and promotion may still be protected under **member-state unfair competition rules**, offering a supplementary pathway when registered 3D marks or designs are unavailable.

CASE

P&G ZzzQuil NATURA v. Dolce Sonno (Turin, Italy 2023)

Preliminary injunction granted; packaging with acquired market recognition protected under member-state unfair competition law despite no registered 3D mark.



United Kingdom: Passing Off



UK: Common Law "Passing Off" as the Primary Approach

Three Elements of Passing Off

- **Goodwill** - plaintiff possesses it
- **Misrepresentation** - defendant's conduct constitutes it
- **Damage** - actual damage to plaintiff

Higher evidentiary threshold, with greater focus on protecting business reputation.

SIGNIFICANCE

UK courts consistently apply **strict scrutiny to medical and medical device appearance protection**, requiring clear proof of source identification and excluding functional features.

CASE

Gama Healthcare Ltd v. Pal International Ltd

(Intellectual Property Enterprise Court 2016)

Product: Clinical disinfectant wipes: Gama's **Clinell** vs Pal's **Medipal**

Claim: Gama alleged Pal's packaging was too similar

Holding: Passing off claim **dismissed**

Key Reasons

No independent goodwill: "Clinell" is source-identifier

No sufficient confusion risk: Professional buyers

Intent to reference ≠ deception: Pal deliberately referenced Gama's packaging, but no misrepresentation



VS



Comparative Summary

Dimension	China	United States	European Union	United Kingdom
Post-Expiry Succession Pathways	UCL (influential trade dress) + Copyright + Trademark	Trade Dress (Lanham Act) + Copyright + Trademark	Member-state UCL + Copyright + Trademark	Passing Off + Copyright + Trademark
3D Trademark Registration Threshold	Distinctiveness + Non-functionality	Secondary meaning + Non-functionality (<i>for product shapes</i>)	Art. 7(1)(e) EUTMR - 3 pillars: (i) nature of goods; (ii) technical result; (iii) substantial value	Distinctiveness + Non-functionality
UCL / Trade Dress Requirements	Influential trade dress + Distinctive features	Distinctiveness + Non-functionality + Likelihood of confusion	Varies by member state	Goodwill + Misrepresentation + Damage
Copyright for Works of Applied Art	High difficulty	High difficulty	Moderate	High difficulty

Practical strategy and key takeaway



Practical Strategy: A Three-Phase IP Framework

Protection starts at creation

Phase 1: Pre-launch Preparation	Phase 2: Commercial Operation	Phase 3: Pre-expiry Transition
1. Design Registration File for core non-functional visual features 2. Copyright Dual Protection Copyright registration for packaging designs, illustrations, and graphic elements 3. Creation Evidence Retain manuscripts, timestamps, communication records	1. Unified Visual Identity Standardize core visual elements across all channels 2. Systematic Evidence Collection Sales data, advertising spend, media coverage, and exhibition records 3. Market Monitoring Routinely monitor; Preserve infringement evidence	1. Trademark Extension Evaluate 3D trademarks or color combination marks 2. Anti-Unfair Competition Strategy Build evidence chain for "certain influence" 3. Cross-border Risk Complete customs IP recordal

Core Takeaways



Extended Protection

Design expiry ≠ Public domain for trade dress.



Evidence of Influence

Market influence is your strongest remedy.



Holistic IP Strategy

Layered tools beat single reliance.

Key Action: *Document from day one. Diversify registrations. Build a long-term defensive protection.*

Our presence

We have a highly respected and long-established presence in multiple jurisdictions



Top Tier

Asia Pacific,
China,
Middle East,
Africa & Europe



19

Jurisdictions



43

Offices



1000+

People



36

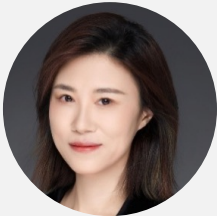
Years



Thank you

ROUSE

 *Contact us*



Flora FANG
Principal, China
ffang2@rouse.com

