WANHUIDA
NEWSLETTER

WANHUIDA
INTELLECTUAL PROPERTY

No. 2025-07

- **n° 81 WHD Insights:**
  IP | Fresh judicial interpretation on criminal IP cases introduces welcome change – but impact on sentencing severity remains unclear

- **n° 82 WHD Insights:**
  PT | China: Assessing inventive step for pharmaceutical combination formulations

- **n° 24 Case:**
  CP | Chinese court denies copyright protection for AI-generated content with insufficient human input in first-of-its-kind ruling

www.wanhuida.com

Expertise
Makes It Possible®

n° 81 WHD Insights: IP | Fresh judicial interpretation on criminal IP cases introduces welcome change – but impact on sentencing severity remains unclear

Zhigang Zhu and Paul Ranjard, 4 June 2025, first published by IAM

On 23 April 2025, China's Supreme People's Court and Supreme People's Procuratorate jointly released the "Interpretation on Several Issues Concerning the Application of Law in the Handling of Criminal Cases Involving the Infringement of Intellectual Property Rights". It took effect on 26 April 2025.

The new Interpretation provides explanations for the implementation of Articles 213 to 219 of the Criminal Law concerning IP crimes, and supersedes the previous 2004, 2007 and 2020 versions.

The revision of the Criminal Law

The Criminal Law was revised in 2021 to extend the crime of counterfeiting registered marks to include service marks.

The concept of "causing major losses" was replaced by "serious circumstances", which focuses more on the concerned party's conduct rather than on the result of the conduct. This broadens the criteria for determining harm and, to some extent, lowers the threshold for criminal prosecution.

The amended law also provides harsher penalties. For Articles 213 (counterfeiting trademarks), 214 (selling goods bearing counterfeit registered trademarks), 215 (manufacturing or selling counterfeit trademark labels), 217 (copyright infringement), and 219 (trade secret infringement), the maximum term of imprisonment has increased from seven to 10 years. The term under Article 218 (selling infringing replicas) has been raised from "not more than three years" to "not more than five years".

Comprising 31 articles, the 2025 Interpretation is now the sole judicial interpretation of the revised Criminal Law.

A deep dive into the new Interpretation

New content

Article 3 explicitly applies the criminal thresholds for the act of counterfeiting a service mark: illegal gains reach 50,000 yuan, or where two or more registered marks

are counterfeited, illegal gains reach 30,000 yuan.

The new Interpretation defines "two or more registered trademarks" in Article 7, which clarifies that the marks must "identity goods or services from different sources". In other words, if a party counterfeits two or more different trademarks, but these point to the same product or service, this does not count.

Article 4 recognises two additional circumstances that show when the seller knows that the goods are counterfeit:

- purchasing or selling well below market price without legitimate reason; and
- concealing or destroying infringing goods or accounting records or providing false evidence after being found out by administrative enforcement authorities or judiciary.

Articles 3, 5, 6, 10 and 14 lower the entry thresholds where a defendant reoffends within two years of a prior IP-crime conviction or administrative penalty.
Article 28 sets out that illegal gains equal all infringing revenue minus purchase costs of raw materials for the infringing goods or the purchase price of the infringing goods that had been sold. For service providers, costs of any goods used are deductible. However, profits earned by charging service, membership, advertising or similar fees must be classified as illegal gains.

The Interpretation closes the goods/labels separation loophole, which is a trick employed by counterfeiters that are well informed of the law. They use it to ensure that the products and the counterfeit labels remain detached as late as possible, making evidence of the crime more difficult to establish. Article 29 provides that, if there is evidence showing that the products are intended to bear the counterfeit mark, the value of the finished products (even if not yet or fully affixed with the fake labels) will be counted in illegal turnovers.

Article 22 explicitly includes the following parties within the potential scope of accomplice liability – provided that their knowing participation can be proven:

- payment processors;
- warehousing companies;
- couriers;
- server-hosting providers; and
- cloud-storage operators.

Amended rules

Under Article 6 – the offence of manufacturing or selling counterfeit trademark labels – the minimum quantities or illegal gains have been approximately halved. For online copyright infringement (Article 13), the download threshold has dropped from 50,000 to 10,000 and an alternative click-through threshold of 100,000 has been added. For selling infringing copies (Article 14), the illegal-gain threshold has fallen from 100,000 to 50,000 yuan.

In terms of higher fines, Article 25 raises the maximum fine from fivefold to tenfold the amount of illegal gains. Articles 3, 5 and 13 now require illegal gains or business turnovers to reach 10 times (increased from five) the basic threshold to constitute "particularly serious circumstances", which carry sentences of up to 10 years of imprisonment.

The wording of Article 24 has changed from "may be leniently punished at discretion" to "may be leniently punished according to law". It also states that where the offence is minor, prosecutors may decline to indict or courts may exempt punishment; behaviour that is "obviously minor and causes little harm" is not treated as criminal.

Key takeaways

Outlining the new list of accomplices creates a powerful deterrent. When receiving a rights holder's cease-and-desist letter, these intermediaries are far more likely to cooperate in order to avoid criminal implication. Similarly, lowering the criminal thresholds and raising fine ceilings strengthens the fight against IP crime – especially the online dissemination of copyrighted works – and is an area where the new measures have already shown marked results.

The new rule targeting goods-and-label separation is another significant step forward. What remains unclear, however, is whether it will apply when infringers store labels and goods separately, ship them in separate consignments and then instruct purchasers to affix the labels themselves.

While these are all welcome developments, a more cautious view should be taken with regard to raising the threshold for "particularly serious" offences while lowering the bar for lenient treatment. Under China's Criminal Law, IP infringement cases classified as "serious" carry sentences of up to three years and remain eligible for probation – and, in practice, most such cases do result in suspended sentences. Only offences deemed "particularly serious" are ineligible for probation. By increasing this threshold and broadening access to leniency, the new Interpretation is likely to make actual custodial sentences for IP crimes even rarer.

In short, the 2025 Interpretation better aligns criminal enforcement with today's infringement realities and will be welcomed by rights holders, though its impact on sentencing severity remains to be observed.

n° 82 WHD Insights: PT | China: Assessing inventive step for pharmaceutical combination formulations

Wu Xiaohui, 10 June 2025, first published by MIP

A 'combination formulation' refers to a pharmaceutical formulation containing two or more active ingredients. Leveraging synergistic effects, a combination formulation often exhibits better efficacy and fewer adverse reactions than single-component drugs. The inventive step assessment of a combination formulation has been closely watched by practitioners in the pharmaceutical industry. A recent invalidation decision – No. 580332, made by the CNIPA on September 30 2024 – provides some guidance in this regard.

Case summary

Egis Pharmaceuticals plc owns invention patent No. 200980138060.7 (the Subject Patent), which relates to a pharmaceutical composition containing amlodipine besylate and bisoprolol fumarate.

On March 15 2024, a Chinese biopharma company launched an invalidation action against the Subject Patent, challenging its inventive step and citing multiple combinations of prior art, using Evidence 2 and Evidence 3 as the closest prior art.

Claim 1 of the Subject Patent protects a tablet prepared by direct compression. The tablet contains amlodipine besylate and bisoprolol fumarate packaged in cold-formed blisters with aluminium foil-covered OPA AL PVC composite foil, along with pharmaceutically acceptable excipients, as well as a compound of formula (3), which weighs less than 0.5% of the active ingredients. The tablet does not require separate processing of amlodipine besylate and bisoprolol fumarate during its preparation.

Evidence 2 discloses a direct compressing tablet of amlodipine maleate prepared by the wet granulation method. The resulting tablets contained below 0.5% of impurity 6 (i.e., the compound of formula (3) in the Subject Patent) in the initial phase and after one month when the temperature is controlled at 40°C and the relative humidity 75%.

Evidence 3 discloses that conventional approaches fail in combining the two drugs, either by mixing amlodipine besylate and bisoprolol fumarate with diluents such as lactose and microcrystalline cellulose and then granulating the mixture with starch paste, or by separately granulating and drying the two drugs, and subsequently compressing the mixture into tablets. That is because, as acid addition salts, amlodipine besylate and bisoprolol fumarate may react with each other, leading to chemical instability, thus making the traditional methods of making tablets unviable, unless there is a method to avoid harmful chemical reactions between the two drugs.

The CNIPA's reasoning

The CNIPA's panel identified the following differences between Claim 1 and Evidence 2:

- The active ingredients in the Subject Patent are amlodipine besylate and bisoprolol fumarate, whereas Evidence 2 uses amlodipine maleate;
- The Subject Patent specifies that the two active ingredients do not require separate processing; and
- The Subject Patent selects cold-formed blisters with aluminium foil-covered OPA AL PVC composite foil as packaging.

The patent specification dictates that amlodipine besylate and bisoprolol fumarate exhibit chemical incompatibility, leading to the formation of impurity compound (3) upon contact. The invention aims to prepare a stable pharmaceutical composition of the two drugs without separate processing by selecting specific packaging and conditions. Data included in the specification indicates that the two active ingredients are not sensitive to temperature to such an extent that mere contact would induce reactions. When prepared by direct compression and packaged in cold-formed OPA AL PVC composite foil blisters with aluminium foil coverage, the composition could achieve a favourable impurity control effect. Based on these distinguishing technical features and the described effects, Claim 1 addresses the technical problem of providing a stable pharmaceutical product containing bisoprolol fumarate and amlodipine besylate through specific preparation methods and packaging.

The panel found that Evidence 3 neither identifies the impurity formed by the reaction of the two active ingredients nor provides the teaching to avoid separate processing of the ingredients. On the contrary, it explicitly instructs separate processing of each active ingredient with excipients before combining them into the final formulation.

Although Evidence 2 suggests that an amlodipine base reacts to form the compound of formula (3), it attributes the impurity formation to the presence of water or moisture during preparation. Evidence 3, however, attributes the instability to the potential chemical reaction between the two acid addition salts, without specifying that the impurity is definitely the compound of formula (3). Even considering the structural relationship between fumaric acid and maleic acid, which suggests that bisoprolol fumarate may react with amlodipine besylate, Evidence 3 teaches that the two active ingredients must first be separately mixed with excipients before being combined for tableting or encapsulation. Thus, combining Evidence 2 and 3 would result in a technical solution requiring separate processing of the active ingredients.

The panel specifically noted that although the active ingredients, impurities, packaging materials, and even preparation methods used in the Subject Patent are taught in the prior art or conventional in the field, this does not make any pharmaceutical formulation obvious relative to the prior art. The development of pharmaceutical formulations typically begins with selecting appropriate formulation strategies to overcome any identified bioavailability issues of active ingredients,

meaning the technical problem is usually the starting point for formulation development.

The key issue in this case is whether a person skilled in the art, being aware of the reaction between amlodipine besylate and bisoprolol fumarate from the prior art, would still seek to prepare a formulation without separate processing. However, given the known reactivity upon contact, the most conventional approach, as demonstrated by Evidence 3 and other prior art, would be to process the two ingredients separately or minimise their contact. Therefore, the prior art not only lacks motivation to combine Evidence 2 and 3 but also shows that solving the stability issue of combining two easily reactive ingredients without separate processing is inherently non-obvious.

Ultimately, the panel concluded that Claim 1 possesses an inventive step over each and every closest prior art and therefore issued invalidation decision No. 580332, maintaining the validity of the Subject Patent.

Commentary on the CNIPA panel's findings

In this case, the panel took a holistic approach in analysing Evidence 2 and 3, dissecting the technical teaching by combining the two prior arts, and concluded that the mere replacement of the active ingredients in Evidence 2 with those in Evidence 3 would contradict the teaching of Evidence 3.

In assessing the technical teaching for an inventive step, it is essential to evaluate the prior art as a whole, by taking into account the technical facts disclosed in the prior art and identifying the technical teaching provided, from the perspective of a person skilled in the art. When the prior art contains both supporting and contradictory information, an assessment should be made within the boundary of the prior art, benchmarking against the technical know-how of a skilled person.

The decision also affirms that whether the raw materials, excipients, or preparation methods used in a formulation are conventional shall have no bearing on the assessment of their contribution to inventiveness. This finding underpins the significance of adopting a holistic approach in the inventiveness assessment as it would be pivotal to reach a sound conclusion on whether there is a teaching leading to the claimed technical solution, and solving the technical problem. Otherwise, the assessment would become moot, as when a technical solution is broken down into isolated technical features, the chances are that most, if not all, the features will be covered by the prior art.

This decision also underscores that in drafting patent applications, applicants need to articulate the uniqueness of the technical problem, highlight the synergistic effects of technical features, and validate these through experimental data.

n° 24 Case: CP | Chinese court denies copyright protection for AI-generated content with insufficient human input in first-of-its-kind ruling

Xiaoquan (Claus) Zhang, 28 May 2025, first published by IAM

On 19 March 2025, the Zhangjiagang Court of Jiangsu Province handed down a decision dismissing a copyright infringement and unfair competition suit that designer Feng Runjuan brought against manufacturer Kuashi Plastic, distributor DongShan Culture, a natural person Aisha Zhu and others concerning a children's chair with a butterfly shaped back.

Feng filed an appeal before the Suzhou Intermediate Court to challenge the dismissal, but the court interpreted her failure to pay the appeal fees as withdrawal, thus rendering the first-instance decision final.

Case background

Feng cited three AI-generated images (Figure 1), which she allegedly created using the Midjourney platform by entering the prompt: "Children's chair with jelly texture, shape of cute pink butterfly, glass texture, light background". She shared both the prompt and resulting images on RedNote, a Chinese social media app, on 15 August 2023.

Figure 1. Feng's AI-generated images

Five days later, Feng was approached by Aisha Zhu on behalf of the accused companies, who offered to commercialise and mass produce Feng's design.

After the negotiation failed, Zhu used Feng's publicly shared prompt to generate similar designs, made some tweaks and proceeded to manufacture and sell chairs featuring the below design (Figures 2 and 3) in January 2024.

Figure 2. The accused design

Figure 3. The accused design

In June 2024, Feng brought a suit against the defendants before the Zhangjiagang Court, requesting cessation and destruction of the inventory and mould, as well as damages of 200,000 yuan.

Court decision

The dispute ultimately boiled down to whether the AI-generated images qualify as original works that are eligible for copyright protection.

To support her claim, Feng attempted to recreate the images of Figure 1 using almost identical prompts – but to no avail. She acknowledged that the randomness and the inherently unpredictable nature of AI-generated outputs made her unable to reproduce the exact same images.

Figure 4. The recreated images

The court observed that the recreated versions differed significantly from the originals and concluded that this divergence demonstrated a lack of substantiated author-driven expressions. The court elaborated on the parameters in assessing the copyrightability of AI-generated content. It held that a user must provide a verifiable creative process that shows the:

- adjustment, selection and embellishment of the original images by adding prompts and changing parameters; and
- deliberate, individualised choices and substantial intellectual input over the visual expression elements, such as layout, proportion, perspective, arrangement, colour and lines.

As Feng failed to meet this threshold, the court ruled that the initial images did not qualify as original works eligible for copyright protection.

Clarification on AI-generated content protection threshold

This is the first Chinese court decision that explicitly denies copyright protection to content predominantly generated by AI without substantial human input. Rather than categorically denying the copyrightability of AI-generated content, the decision draws a line between AI-generated and AI-assisted content.

The court used the level of human input as a litmus test to assess the originality of AI-generated content. Content that is autonomously created by AI does not qualify as a "work" under copyright law. Conversely, content generated by users employing AI tools and contributing original and creative input may still qualify for protection. This practice aligns with the methodology introduced in the 2025 US Copyright Office report “Copyright and Artificial Intelligence, Part 2: Copyrightability”, which underscores the need to evaluate the human role in AI-generated works.

Key takeaways

This ruling highlights a fundamental principle – copyright law protects human creativity, not machine output. Humans should dominate the creation process, not the other way around. Putting AI in the driver’s seat is like putting the cart before the horse. Creators using AI tools should ensure that their creative process is properly documented and could be reproduced, particularly the specific contributions that they made to the final work.

It is also worth noting that the court reaffirmed the distinction between ideas and expression. It found that prompts fall within the realm of ideas, which are not eligible for copyright protection. This is a welcome decision as the free use of publicly shared prompts is conducive to promoting openness and collaboration in this space.