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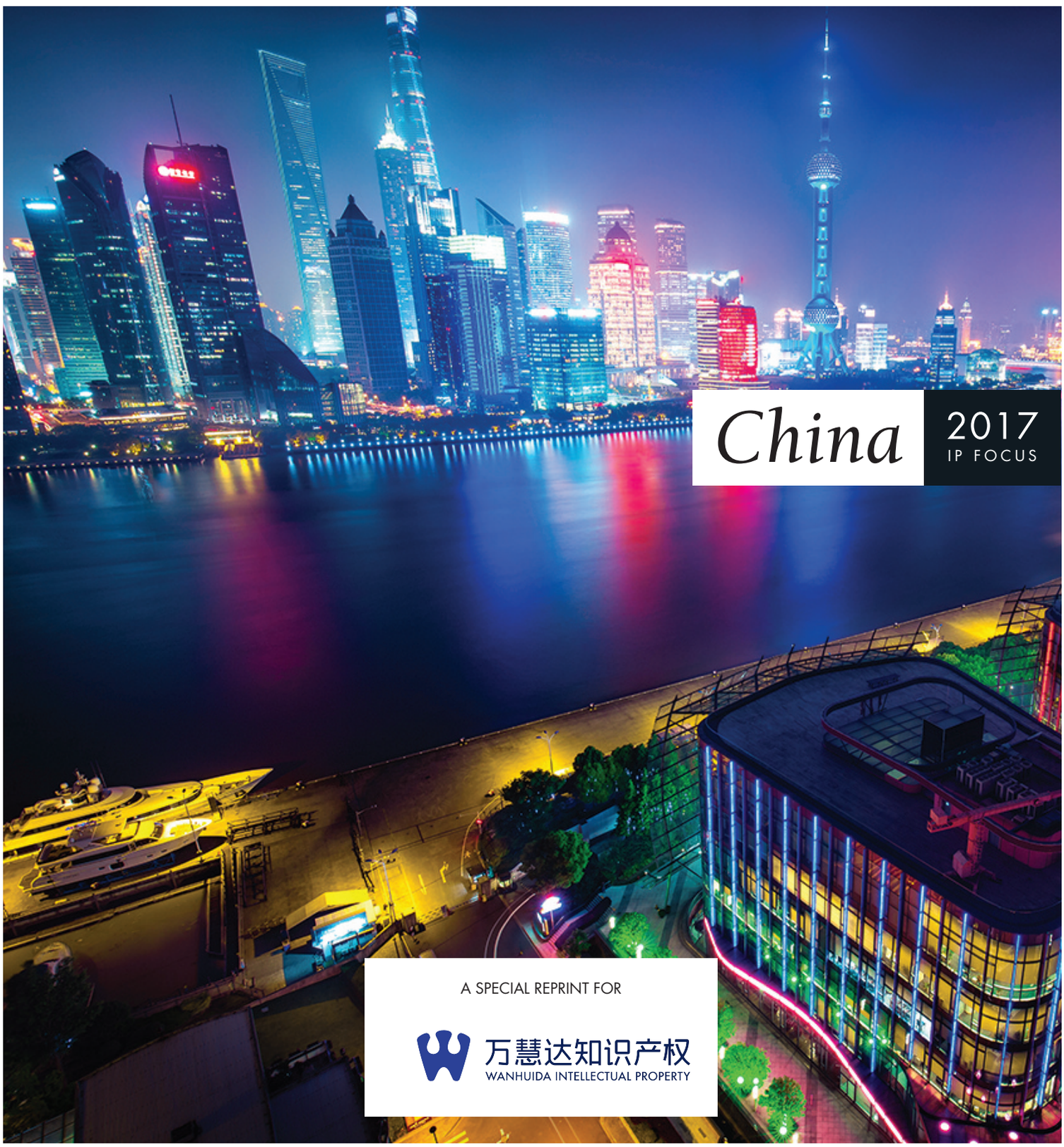
THREE SUPREME COURT CASES ON PHARMACEUTICAL PATENTS



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Three Supreme Court cases on pharmaceutical patents

S Sam Li and Honghui Hu of Wan Hui Da – Peksung IP Group explain three important Supreme Court cases on pharmaceutical patents

With some ten thousand cases a year, Chinese law on patent litigation is dynamic. Courts, particularly the Supreme People's Court (the Court), lead the advancement of the law. This article seeks to convey a sense of these developments through three key decisions.

PHARMACEUTICALS

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The *Simcere* Case – amendment of patent claims

The Patent Law Article 33 limits amendments of patent claims to the original disclosure and scope of protection. The Patent Examination Guideline (the Guideline) only permits amendments if they can be directly and unambiguously determined from the original disclosure. It further limits the types of amendment to: deletion of claims, combination of claims and deletion of technical solutions within a claim. The Guideline's restrictive prescriptions and rigid applications give rise to broad dissatisfaction. From 2010, the Court has taken up eleven cases addressing issues involving amendments of claims to remedy the situation. The Simcere case is an example of their efforts.

Simcere Pharmaceutical held a patent for anti-high blood pressure formulations of amlodipine and irbesartan. In an invalidation proceeding, Simcere proposed to amend a claim establishing its formulation of "a pharmaceutical composition comprising a weight ratio of 1:10-30 of active ingredients amlodipine or its physiologically acceptable salt and irbesartan." The proposed amendment narrowed the ratio to simply 1:30. The Patent Reexamination Board (PRB) rejected the amendment because the ratio 1:30 cannot be directly and unambiguously determined from the original disclosure. The PRB's decision was maintained by the court of first instance but overturned by the court of second instance. The PRB petitioned the Court to review the case.

The Court permitted the amendment. It found the amended content in the original disclosure without applying the direct and unambiguous standard. Specifically, the Court opined that the ratio of 1:30 was disclosed in examples in the patent specification. The examples included an optimal combination of amlodipine over irbesartan as 1:30 mg/kg, a dosage range of 2-10:50-300 mg and preparations with the two ingredients in weight relationships of 2.500:75.000 mg and 5:150 mg. The examples did not give an explicit description of a generally applicable ratio of 1:30. But examples could only describe specific weights. These weights are all consistent with the claimed ratio. To a person skilled in the art, the ratio is disclosed. The Court also stated that an inquiry into whether all weights corresponding to the ratio can fulfill the inventive purpose should be made under Article 26.4 instead of Article 33.

The Court recognized that the amendment was not a typical deletion of technical solutions. It however noted that the justification for limiting the types of amendments is to protect public reliance on claims and to prevent broadening of their scope, not to punish imperfect claim drafting. In this case, the amendment did not broaden the scope of the claim, it clarified it. The Court also stated that the list of permitted amendments in the Guideline is not exhaustive.

The Court's efforts have advanced rationales for practice concerning claim amendments. A newly released Guideline in February also reflects a more flexible approach. It states that "the specific types of amendments are generally limited to deletion of a claim, deletion of a technical solution, *further limitation to a claim [by reciting features in other claims] and correction of an apparent error*".

The *Telier* case – close-end claims

The Guideline allows two types of claims for compositions: open-end claims, typically with claim language like "comprising," and close-end claims, typically with claim language like "consisting of".

An open-end claim would cover a composition with the claimed components regardless of whether the composition also has other components, while a close-end claim would cover a composition with the claimed components only. The Guideline however does not bind courts and had not been expounded in the context of an infringement case. The *Telier* case for the first time construed a close-end claim in the context of a pharmaceutical composition – whether the addition of pharmaceutically inactive excipients would place a composition outside the scope of a close-end claim.

The case involved a patent covering a composition of lyophilized powder for injection consisting of adenosine disodium triphosphate and magnesium chloride. The defendant's product had the two claimed ingredients but with an added inactive excipient of arginine, known to in-

crease composition stability. It was added together with sodium bicarbonate in the formulation process and retained in the final product. Adding ingredients in the formulation process is common. The issue was whether such routinely added ingredients in the formulation process would place the resulting composition outside the scope of a close-end claim. The courts of the first and second instances both found infringement because the defendant failed to prove that the added excipient substantially affected the pharmaceutical function of the composition.

Before the Court, the patentee argued for infringement either because the accused product bore the essential features of the claim – containing the two active ingredients, or because it was equivalent to the claimed composition as the addition of arginine is routine in formulation processing.

Because the patentee's claim for the formulation was drafted as a close-end one, which did not include the added arginine, the Court took issue with it. It held that the practice of drafting close-end claims had been around since 1993, with consistent directives from the Guideline. It held that there was a public expectation that such a claim would not cover a composition with additional components. The patentee thus had a duty to know the terms of the art and should bear losses resulting from inappropriate claim drafting. Moreover, the doctrine of equivalence should not apply as it would defeat the purpose of close-end claims.

The decision in the *Telier* case holds a strict but clear construction of close-end claims for compositions. The case led to a provision in the Court's judicial interpretation of March 2016, directing courts not to find infringement of a close-end claim "unless the additional features are unavoidable impurities" and making the holding generally applicable.

The *Lilly* case

Low damages for infringement have been a perennial problem. The Patent Law prescribes four methods for damage determination: patentee's loss, infringer's gain, multiples of royalties and discretionary damages capped at Rmb1,000,000. Most cases use the last option due to lack of evidence and the underdevelopment of the other methods. Damages are critical to the pharmaceutical industry for sustaining innovation.

The Court has been leading efforts to increase damages by encouraging exploratory practices, such as imposing damages above the statutory cap and demanding production of financial information held by defendants, coupled with aggressive adverse inference. Consequently, sporadic large damage awards have appeared but reasoned guidance is wanting.

In this case, Lilly sued Watson for infringing its patented manufacturing process for olanzapine, an antipsychotic drug. The Jiangsu Higher People's Court found Watson infringing and ordered it to pay damages of Rmb500,000 for the period of infringement up to 2003. The decision was based on the fact that olanzapine was a "new product" and that Watson had failed to prove the difference of its manufacturing process. Although Watson asserted the use of its own process as filed with the regulatory authority, the court found that, according to a technical appraisal, the process did not work.

With infringement confirmed, Lilly then sued for damages resulting from Watson's use of the process between 2003 and 2011. Lilly gathered evidence from two sources. Based on a report assessing Watson's potential losses if it stopped manufacturing, Watson's monthly profit for selling olanzapine was about Rmb1,660,000 and the total profit for the relevant period was Rmb151,060,000. An extensive market investigation indicated that for the relevant period Watson had hospital sales of Rmb186,914,143, retail sales of Rmb64,975,343. Subtracting the cost of materi-

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als (Rmb86,522,830), the gross profit was Rmb165,366,656. Picking the lower of the two profit numbers, Lilly claimed damages of Rmb151,060,000.

The Jiangsu Higher People's Court awarded Lilly damages of Rmb3,500,000. Both parties appealed to the Court. Unfortunately, the Court did not address the damage issue. Instead, it re-opened the issue of infringement. Taking in new trade secret evidence submitted by Watson, the Court declared itself satisfied with Watson's assertion of using its own manufacturing process, different from the claimed process. We'll have to wait for another case for the Court's guidance on damage determination.

Courts are expected to play a leading role in IP protection. Future decisions will give further guidance as they provide specific context for the application of the statutory laws, which inevitably fall behind facts. The precedential value of cases is gaining recognition in China. The Court has required all decisions be made public promptly and encouraged the use of cases in judicial decision making. We expect more illuminating cases from courts, particularly the Court.

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