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Analysis of technical suggestions for pharmaceutical inventions in China

On 20 July 2022, examiners of the China National Intellectual Property Agency (CNIPA) explained the issue of technical suggestions based on the invalidation case of "quinoline derivatives for the treatment of latent tuberculosis (LTB)". The patents related to the world's first anti-TB drug "bedaquiline", and are concerned with the invention of a new medicinal use of a known drug. This is one of the top 10 invalidation cases in 2021 selected by CNIPA. The explanation given by the examiners and the results of reexamination is particularly helpful for foreign pharmaceutical patentees because:

1) the patent owner of the case is a foreign pharmaceutical company;

2) the issues involved in the case are the issues that foreign pharmaceutical companies encounter frequently, including insufficient disclosure and lack of inventive steps; and

3) the explanation provides more insights regarding how the panel in the CNIPA determines whether there is technical suggestions in the prior art in the pharmaceutical field.

Case background

The petitioner (an individual) filed an invalidation request for two patents (Quinoline derivatives for the treatment of LTB and Use of substituted quinoline derivatives for the treatment of drug-resistant mycobacterial diseases) against the patentee Jessen Pharmaceutical at the CNIPA. The petitioner submitted a few pieces of evidence in proving that the patents lack inventive steps. After examination, the panel decided that the patents were valid.

In short

We should take the view of the person skilled in the art when determining whether there are suggestions in the prior art. The key factors are as follows:

1. Examining the prior art as a whole, to avoid being limited to its literal meaning, and to prevent over-interpretation or subjective assumption of its content.
2. Determining if the prior art provides suggestions to the application of the distinguishing feature of an invention in solving the technical problem of the invention, only the content reasonably related to the solution of the problem of the invention may constitute suggestions.
3. In determining whether there is a suggestion, we should focus on whether the introduction of such a distinguishing feature expects success in solving technical problems. The lack of reasonable expectation of success makes it difficult to form a motivation for the improvement of the prior art.

Analysis of the case

The analysis provided further guidance on the third step of the three-step approach in determining the inventive step of an invention, in particular, whether there are suggestions in the prior art.

Three-step approach	Further guidance from the CNIPA analysis
Determine whether the claimed invention is obvious to a person skilled in the art	1. Examine the prior art as a whole 2. Determining if the prior art provides suggestion for the application of the distinguishing feature of an invention in solving the technical problems of the invention 3. The expectation of success will be one of the key factors in determining the inventive steps of an invention. Only if there were expectations of success, the person skill in the art would be motivated to improve an invention.

Examination of Use of substituted quinoline derivatives in the treatment of drug-resistant mycobacterial diseases

Examiners studied the Evidences 1 and 4 submitted by the petitioner thoroughly and concluded that:

Evidence 1 only uses susceptible strains for experiments and does not mention drug-resistant mycobacterial. Evidence 4 discloses the principle of the treatment of drug-resistant mycobacterial diseases, but does not mention "bedaquiline" and whether it can treat drug-resistant TB. Evidence 4 also points out that susceptibility testing is required and based on the results of the test to decide which drugs should be used to treat drug-resistant TB. As a result, it reduced the predictability of the effect after drug replacement. Therefore, even combining Evidence 1 and Evidence 4, a person skilled in the art is unlikely to adopt the suggestion of the prior art to treat drug-resistant TB.

Examination of the Quinoline derivatives for the treatment of LTB

Examiners studied Evidence 1 and 12 submitted by the petitioner thoroughly. The conclusion is as below:

1. Review the content of the prior art

a) Evidence 1 discloses that "bedaquiline" has antibacterial activity in vitro against mycobacterium tuberculosis (TB), and the experiments were conducted on bacteria that are in the lag phase and the log phase rather than LTB bacteria. There is no discussion or documentation for the LTB.

b) The concept that the drug provides a method to treat patients "at risk of developing mycobacterial disease" in Evidence 1 is relatively broad and covers all situations at risk, such as the destruction of the autoimmune system after HIV infection.

c) Evidence 12 fails to disclose "bedaquiline" in the whole content.

Therefore, it is difficult for a person skilled in the art to conclude that "bedaquiline" can be used for the treatment of LTB.

2. Identify teaching of the prior art and its relationship between the prior art and the invention

a) Background usually summarizes the development of prior art. It is necessary to determine if the information disclosed in the background provides relevant teaching or guidance for solving technical problems.

b) Background of Evidence 1 only shows that a drug can achieve the desired effect if it shortens the treatment length and reduces the administration frequency. However, the Evidence itself does not indicate that "bedaquiline" has been used to achieve the aforesaid desired effect. Under the condition that Evidence 1 did not achieve the desired effect of shortening the length of the treatment, even though Evidence 12 taught that drugs with good killing effect and rapid-onset are effective to target semi-dormant bacillus, there is no motivation for those skilled in the art to use "bedaquiline" to treat LTB.

3. Determine if there are expectations of success by analyzing the function of the prior art and the invention

a) Evidence 1 discloses that "bedaquiline" can effectively inhibit lag and log phases of mycobacterium tuberculosis. It also provides teaching on the direction to develop new drugs for TB. However, bearing in mind that it does not mention LTB.

b) Evidence 12 discloses different treatments for eugonic tubercle bacillus and dormant bacillus. Drugs that are effective for active tuberculosis are not necessarily effective for LTB. It is always more difficult to treat LTB.

Combining the two pieces of evidence, it is difficult for a skilled person in the art to form a reasonable expectation of success based on the teaching of the prior art that bedaquiline can effectively treat LTB. Therefore, a person skilled in the art is unlikely to come up with the present invention by simply learning from the suggestion of the prior art.

Source of the article: China Intellectual Property News, written by Xiaohong Ni, Jianxia Shao and Jun Li. The original article is available on CNIPA's website here (Chinese only).

CNIPA released the Guidelines for IP Protection at Exhibitions

On 22nd July 2022, the China Intellectual Property Administration (CNIPA) released the Guidelines for IP Protection at Exhibitions. Implementation of the Guidelines further strengthens the IP protection policy in China and guides the role of IP departments and workstations at the exhibitions.

Applicable scope

All the online and in-person trade fairs and exhibitions are held within the border of the People's Republic of China (Article 2).

Pre-exhibition IP protection (Article 8)

The local IP office may work with other relevant departments, such as the IP enforcement department to assist the event organizers in setting up a workstation at the exhibition following the national requirements. At the request of the event organizer, the local IP office has duties to coordinate relevant staff, law enforcement personnel, professional technical personnel, and legal professionals to perform their duties at the workstation. These include:

1. handling complaints related to IP rights;
2. mediating infringement disputes during the exhibition period;
3. offering legal advice concerning infringement;
4. forming a judgment on the complaints of suspected infringement and handing over its judgment to the exhibition organizer to follow up;
5. transferring the relevant complaints and materials to the local IP office where the exhibition is held, and delivering evidence to relevant IP enforcement departments; and
6. summarizing and analyzing the IP-related information collected during the exhibition.

IP protection during the exhibition

The workstation must accept on-site complaints about the suspected infringing products and acts during the exhibition (Article 11). The complainant should provide the following information to the workstation:

1. complaint letter which includes the basic information of the complainant and the respondent, the facts, reasons, and relevant evidence to prove the infringement of the exhibitor;

2. valid IP ownership certificate, including patent certificate, copy of patent grant publication, patent owner's identity certificate, trademark registration certificate, trademark owner's identity certificate, copy of geographical indication publication, geographical indication right owner's identity certificate, and other relevant materials;

3. if the complainant instructs an agent to file the complaint, the complaint should also include the power of attorney and the identity certificate of the agent. The power of attorney should include the information of the matter instructed to the agent and the power of the agent, and it should be signed or sealed by the client; and

4. other relevant materials (Article 12).

The workstation will promptly notify the event organizer as well as the respondent upon receiving the complaint (Article 13). If the respondent fails to submit written statements and evidentiary materials without justifiable reasons within 24 hours after receiving the notification, or the infringement of the complained exhibited item has been confirmed by valid legal documents, or the respondent admits the claim, the workstation shall coordinate with the event organizer to take timely measures, including but not limited to dismantling, covering-up, shielding, disconnecting network of the respondent's booth / complained products, etc. (Article 14)

The Guidelines mark a positive development of IP protection in China. Although foreign entities may find themselves having difficulties in entering China to attend trade fairs/exhibitions, the Guidelines provide foreign entities with a strong backup if they encounter any infringement acts at exhibitions in China.

Interpretation of Bolar exceptions in China*

Recently, the Court of Intellectual Property of the Supreme People's Court concluded that two cases, which concerned the offer for sale of a patented pharmaceutical product, do NOT fall within the scope of exception of patent infringement for drugs and medical devices that are under administrative examination and approval, as stipulated in the Patent Law. This is a friendly sign to the patentees, especially those patent holders for new drugs or medical devices, who seek to protect their patents in China.

Case Background

The dispute arose between the patent owner, a German multinational pharmaceutical and biotechnology company and one of the largest pharmaceutical companies in the world, and the infringers, a pharmaceutical company, and a life science company based in China. The patent concerned is entitled "Substituted oxazolidinone and their use in the field of blood coagulation" with patent no. ZL00818966.8, of which the term of protection is expired.

The infringers displayed "Rivaroxaban Tablets" and "Rivaroxaban API" (the products) on its official website and at the 18th World Pharmaceutical API China Exhibition, with packaging boxes and bottles that printed the infringers' registered trademarks.

The court of first instance held that the products fell within the protection scope of the patented drug of the patent owner, the offer for sale constituted patent infringement, and the offer for sale did not fall into the exception provisions for the drugs and medical devices that are under administrative approval of the Patent Law. The court issued an administrative order which asked the infringers to stop the offer for sale and rejected its claim.

The infringers appealed to the Supreme People's Court, holding that their activity has a group of specific target audiences. Their target audiences are companies that are planning to develop biosimilars of rivaroxaban. At the same time, the infringers claimed that they have not provided information on the price and supply volume of the products so the products are not saleable. The purpose of advertising the products is not to sell, and they had no intention to sell the products. Therefore, their activities do not constitute an offer for sale. The infringers reiterated that its activities shall be subject to the exceptions of infringement for drugs under administrative examination and approval in the Patent Law.

Supreme People's Court upheld the decision of the court of the first instance. In addition, the court opined that regardless of whether the offer for sale has a specific target audience when the description of the products in the sale is clear and concrete, it constitutes an offer for sale. Offer for sale may be either an offer or an invite to offer. Lack of information such as price, supply volume, lot number, or any other information, which may affect parties entering into a contract, etc. of the products, has no impact to establish an offer for sale. Therefore, without obtaining a license from the patent owner, the infringers displayed the products on their websites and exhibitions constituted an offer for sale.

The final decision is in favor of the patent owner.

Analysis of the case

As to whether the offer for sale is a Bolar exception, the final judgment held that:

> Firstly, it is necessary to clarify who is eligible for the exception (Article 75(5) of Patent Law) and the condition for applying for the exception. Two types of the party concerned are eligible for the exception:
>
> (a) the party concerned who exploits the patent to obtain the information required for administrative examination and approval of drugs and medical devices; or
>
> (b) the party concerned who exploits the patent to obtain the administrative examination and approval of the party concerned in (a).
>
> The former party concerned applies for administrative examination and approval for himself whereas the latter party concerned assists the former party concerned to apply for administrative examination and approval.
>
> If (b) would like to apply the Bolar exception to defend himself, he must prove the existence of (a).
>
> Secondly, the scope of the Bolar exception should be strictly defined and applied. Following the Patent Law, the provision regulates that the Bolar exception is applied to the behavior to provide the information required for administrative examination and approval: (1) the party concerned "manufacture, use, import the drug or the medical device" for himself; or (2) "manufacture or import the drug or the medical device" for the party concerned mentioned in (1). Offer for sale is not mentioned in the provision.

In this case, the infringers failed to submit evidence to prove that they manufactured a drug for an applicant who is seeking to apply for administrative examination and approval to produce rivaroxaban drugs. Therefore, the infringers did not meet the requirement to apply the defense. Offer for sale to unspecific parties goes beyond the scope of the provision of the Patent Law and therefore the Bolar exception cannot be applied.

The infringers argued that if it had not advertised the patented drug online and in-person, it would not have an overall understanding of the market and have no means to obtain information on what organizations are planning to develop biosimilars of Rivaroxaban after the patent expires.

The Supreme People's Court holds that this behavior is not in conformity with the stipulations of the law, and unlawfully damages the legitimate interest of the patentee within the patent protection period. During the patent protection period of the drugs, the offer for the sale of a patented drug does not fall within the scope of the Bolar exception. Also, the offer for sale of the patented drugs or medical devices without obtaining licenses from the patentee may mislead the unspecific audiences to wait for the expiration of the patent, which substantially weakens the protection of the legitimate rights and interests of the patentee.

Conclusion

The Supreme People's Court made it clear that balancing the interest between the patentee and the biosimilar companies is of paramount importance when applying the Bolar exception. The courts should ensure that the public will benefit from the drugs and the medical devices at a lower cost after the expiration of the patent right, and avoid weakening the protection of the legitimate rights and interests of the patentees. Although there is a statute for the exception of infringement, the exception must be strictly interpreted.

The final judgment from the Supreme People's Court has also reflected China's attitude toward IP protection; in particular, rigorously protects patentees' legitimate rights and interests.

Nevertheless, applicants should be careful that Article 75(5) of the Patent Law does not extend the scope of application of the Bolar exception, pesticides, veterinary drugs, agricultural machinery, etc, and only for the "manufacture, use and import the drug or the medical device" when applying for administrative approval for the market.

**Provision regarding Bolar Exception can be found in the Patent Law Article 75(5).*

The analysis in the article is based on the following cases:

Case 1 - (2021) Supreme Court of Intellectual Property Administrative Litigation No. 451 & (2020) Jiangsu Administrative Litigation, First Instance No.261

Case 2 - (2021) Supreme Court of Intellectual Property Administrative Litigation No. 702.& (2020) Jiangsu Administrative Litigation, First Instance No. 262

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