SPC Guiding Case No. 84: Eli Lilly and Company v. Changzhou Huasheng Pharmaceutical Co., Ltd. (Invention Patent Infringement Dispute)

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SPC Guiding Case No. 84

Discussed and adopted by the Judicial Committee of the Supreme People's Court; issued on March 6, 2017

Keywords

Civil; infringement of invention patent; invention patent for a pharmaceutical preparation process; protection scope; technical investigator; ascertainment of the preparation process of the alleged infringing drug

Holding

1. In a dispute over infringement of a pharmaceutical preparation process patent, in the absence of other contrary evidence, the process filed by the alleged infringing drug with the drug regulatory department shall be presumed to be its actual preparation process. Where there is evidence proving that the filed process of the alleged infringing drug is untrue, the technical source, production regulations, batch production records, filing documents, and other evidence of the alleged infringing drug shall be fully examined, and the actual preparation process of the alleged infringing drug shall be determined in accordance with the law.

2. With respect to complex technical facts such as the preparation process of the alleged infringing drug, technical investigators, expert assistants, judicial appraisal, and consultation with scientific and technological experts may be comprehensively used to ascertain such facts.

Basic Facts

On July 25, 2013, Eli Lilly and Company (also known as Yilai Lili Company) sued in the Jiangsu Higher People's Court (hereinafter "Jiangsu High Court"), alleging that it owned the process invention patent No. 91103346.7 in question, and that olanzapine, the drug prepared by the patented process, was a new product. Changzhou Huasheng Pharmaceutical Co., Ltd. (hereinafter "Huasheng Company") used a preparation process falling within the protection scope of the patent in question to produce the drug olanzapine and sold it on the market, infringing Eli Lilly's process invention patent in question. For this reason, Eli Lilly brought this action, requesting the court to order: 1. Huasheng Company to compensate Eli Lilly for economic losses of RMB 151,060,000, and for the investigation and evidence-collection fees and other reasonable expenses of RMB 28,800 incurred by Eli Lilly to stop the infringement; 2. Huasheng Company to publish a statement on its website and in the "Medicine Economic News" to eliminate the adverse effects caused by its infringement on Eli Lilly; 3. Huasheng Company to bear the attorney's fees of RMB 1,500,000 incurred by Eli Lilly in this case; and 4. Huasheng Company to bear all litigation costs of this case.

The Jiangsu High Court found in the first instance:

The patent in question was the Chinese invention patent application No. 91103346.7, filed on April 24, 1991, by Lilly Industries Limited of the United Kingdom, under the title "Process for Preparing a Thienobenzodiazepine Compound," with the authorization publication date of February 19, 1995. The patent right in question expired and terminated on April 24, 2011. On March 17, 1998, the patentee of the patent in question was changed to Eli Lilly and Company Limited of the United Kingdom; on February 28, 2002, the patentee was changed to Eli Lilly and Company.

The claims of the patent in question as authorized and published were:

1. A process for preparing 2-methyl-10-(4-methyl-1-piperazinyl)-4H-thieno[2,3-b][1,5]benzodiazepine, or an acid addition salt thereof, the process comprising: (a) reacting N-methylpiperazine with a compound of the following formula, where Q is a leaving group, or (b) subjecting a compound of the following formula to ring-closure reaction.

In July 2001, the Institute of Materia Medica of the Chinese Academy of Medical Sciences (hereinafter "IMM") and Huasheng Company applied to the State Drug Administration (hereinafter "SDA") for new drug certificates for olanzapine and its tablets. On May 9, 2003, IMM and Huasheng Company obtained the "New Drug Certificates" for olanzapine bulk drug and olanzapine tablets issued by the SDA, and Huasheng Company obtained the "Drug Registration Approval" for olanzapine and olanzapine tablets. The "Research Materials and Literature on the Production Process of the Bulk Drug" in the new drug application materials recorded the preparation process, namely adding 4-amino-2-methyl-10-benzyl-thienobenzodiazepine, hydrochloride, methylpiperazine, and dimethylformamide and stirring to obtain a crude product with a yield of 94.5 percent; adding 2-methyl-10-benzyl-(4-methyl-1-piperazinyl)-4H-thienobenzodiazepine, glacial acetic acid, and hydrochloric acid and stirring, then neutralizing with sodium hydroxide to obtain a crude product with a yield of 73.2 percent; and after two refinements, the total yield was 39.1 percent. From the reaction equation analysis, this process was that the compound of Formula IV reacted with methylpiperazine to generate the compound of Formula V, and the compound of Formula V was then debenzylated to obtain the compound of Formula I. In August 2003, Huasheng Company marketed its "Huasheng-Olanzapine" 5mg new antipsychotic drug to the Qingdao Seventh People's Hospital, and its product promotional materials recorded that the main ingredient of the olanzapine tablets was olanzapine, whose chemical name was 2-methyl-10-(4-methyl-1-piperazinyl)-4H-thienobenzodiazepine.

In another case, based on the commission of the Jiangsu High Court, on August 25, 2011, the Shanghai Science and Technology Consulting Service Center issued "Technical Appraisal Report" No. (2010) Jian Zi No. 19. The appraisal report stated that experimental operations conducted according to the process recorded in Huasheng Company's filed "Research Materials and Literature on the Production Process of the Bulk Drug" could not obtain the bulk drug olanzapine. The appraisal conclusion was that the key reaction steps for producing the bulk drug olanzapine recorded in Huasheng Company's filed materials lacked authenticity, and the filed production process was not feasible.

Upon cross-examination, Eli Lilly Company accepted the appraisal report, and Huasheng Company also raised no objection to the appraisal report, but insisted that olanzapine could be produced by the two-step method, except that some content involving trade secrets was not written into the filed materials, and therefore the experts could not produce it based on the filed materials.

Huasheng Company argued that it had not infringed the patent right in question, on the grounds that, from 2003 to the present, it had always used the olanzapine filed production process additionally reported for approval in 2008, and that the filing document had been approved by the SDA on September 8, 2010, and was feasible. Where Eli Lilly had not provided any evidence proving Huasheng Company's production process, Huasheng Company's 2008 olanzapine filed process should be used as the comparison process for determining infringement.

The "Drug Supplementary Application Approval" of the SDA dated September 8, 2010, submitted by Huasheng Company, recorded in the "application content" column: "(1) change the production process that affects drug quality; (2) revise the drug registration standard." The "approval conclusion" column recorded: "Upon review, approval is granted for the change of the production process of this product and the revision of the quality standard. The changed production process, without changing the original synthesis route, only adjusts the solvents and reagents used in the preparation process. The quality standard shall be implemented as attached, with a validity period of 24 months."

In the "Olanzapine Drug Supplementary Application Registration Materials" attached to the above 2010 "Drug Supplementary Application Approval," the explanation content 5.1.1 in the section 5.1 "Research Materials and Literature on the Production Process of the Bulk Drug" was: "According to the actual production situation of our company's olanzapine bulk drug, on the basis of not changing the originally reported production process route, part of the preparation process of olanzapine was adjusted and changed, and the process was optimized, so that the quality of each intermediate of olanzapine was further improved and guaranteed, and the relevant impurities in the preparation process were effectively controlled... Since the process route was not changed, and the crystallization solvent of the last step was also not changed, the structure and crystal form of the compound would not change."

During the second-instance trial before the Supreme People's Court, in order to accurately ascertain the technical facts involved in this case, pursuant to Article 79 of the Civil Procedure Law and Article 122 of the Interpretation of the Supreme People's Court on the Application of the Civil Procedure Law of the People's Republic of China (hereinafter the "Interpretation on the Civil Procedure Law"), the application of Eli Lilly's expert assistant to appear in court was granted; pursuant to Article 117 of the Interpretation on the Civil Procedure Law, the application of Huasheng Company's witness to appear in court was granted; pursuant to Article 78 of the Civil Procedure Law and Article 227 of the Interpretation on the Civil Procedure Law, the staff of the Jiangsu Science and Technology Consulting Center who issued "Technical Appraisal Report" No. (2014) Si Jian Zi No. 02 were notified to appear in court; and pursuant to Articles 2 and 10 of the Interim Provisions of the Supreme People's Court on Several Issues Concerning the Participation of Technical Investigators of Intellectual Property Courts in Litigation Activities, a technical investigator was assigned to appear in court for the first time to question the expert assistant, witness, and appraiser of each party on relevant technical issues.

The Supreme People's Court additionally found in the second instance:

On October 28, 1999, Huasheng Company and IMM signed a "Technical Contract," agreeing that IMM would transfer to Huasheng Company the antipsychotic drug olanzapine and its preparation that it had researched and developed, and that IMM would be responsible for completing the pre-clinical approval materials and applying for clinical trials in Beijing; the acceptance standard and method would follow the new drug approval standard, with acceptance by obtaining the clinical approval and the new drug certificate; and the two parties also agreed in other clauses on the new drug certificate and production approval.

In the "New Drug Clinical Research Application Form" No. (Jing 99) Yao Shen Lin Zi No. 82 filled out by IMM in October 1999, the reaction route drawn in the "preparation process" column was as follows: (reaction route drawing)

On November 9, 1999, the Beijing Municipal Health Bureau, in response to IMM's new drug clinical research application, issued the "On-site Examination Report Form for New Drug Development," recording in the "on-site examination conclusion" column: "The institute has the conditions for developing this raw material, and the original records and experimental materials are basically complete and the content is true."

In June 2001, IMM and Huasheng Company jointly submitted to the SDA the "New Drug Certificate and Production Application Form" (No. (2001) Jing Shen Chan Zi No. 019). In response to that application, on October 22, 2001, the Jiangsu Provincial Drug Administration issued the "On-site Examination Report Form for New Drug Development," recording in the "on-site examination conclusion" column: "Upon on-site examination, the original records of sample preparation and testing are basically complete, the testing instrument conditions are basically available, and the development unit temporarily has no bulk drug production workshop; it now applies for the new drug certificate of this product."

Based on Huasheng Company's application, on May 21, 2009, the Jiangsu Provincial Drug Administration sent a letter commissioning the Drug Safety Supervision Division of the Changzhou Food and Drug Administration of Jiangsu Province to inspect Huasheng Company's olanzapine production site and sample

the products. The Jiangsu Provincial Drug Administration issued the "Drug Registration Production On-site Inspection Report" (acceptance number CXHB0800159) for the inspection and sampling, recording in the "inspection results" column: "In accordance with the relevant requirements for on-site inspection of drug registration, the first inspection of the production site of this variety was conducted on July 7, 2009. The company's organization and personnel, production and testing facilities can meet the production requirements of this variety, the raw and auxiliary materials can be traced, the main raw materials are all fed according to the specified quantities, and the production process is carried out according to the reported process. On August 25, 2009, in accordance with the relevant requirements for on-site verification of drug registration, the batch production records, testing records, raw material use, and inventory records of the three batches of products 70309001, 70309002, and 70309003 were inspected, and sampling was carried out according to the sampling requirements." The "comprehensive evaluation conclusion" column recorded: "Based on the comprehensive evaluation, the on-site inspection conclusion is: passed."

In the "Olanzapine Drug Supplementary Application Registration Materials" attached to the "Drug Supplementary Application Approval" issued to Huasheng Company by the SDA on September 8, 2010, the reaction route drawn in 5.1.2 "process route" under 5.1 "Research Materials and Literature on the Production Process of the Bulk Drug" was as follows: (reaction route drawing)

On March 5, 2015, the Jiangsu Science and Technology Consulting Center, commissioned by Shanghai Fangda (Beijing) Law Firm, issued "Technical Appraisal Report" No. (2014) Si Jian Zi No. 02, whose "appraisal conclusion" recorded: "1. The olanzapine preparation process filed by Huasheng Company with the SDA in 2008 is feasible. 2. Comparing the olanzapine preparation process filed by Huasheng Company with the SDA in 2008 with Eli Lilly's process patent No. 91103346.7, both use secondary amine compounds as starting materials, but the preparation process routes are different, specifically: (1) the key intermediates produced in the reactions are different; (2) the reaction steps are different: Huasheng Company's is a four-step process, while Eli Lilly's is a two-step process; (3) the reaction conditions are different: in the substitution reaction, Huasheng Company uses dimethylformamide as the solvent, while Eli Lilly uses a mixed solvent of dimethyl sulfoxide and toluene as the solvent."

At the second-instance hearing, Eli Lilly expressly stated that it sought protection of method (a) of claim 1 of the patent in question in this case.

Judgment

On October 14, 2014, the Jiangsu Higher People's Court rendered Civil Judgment No. (2013) Su Min Chu Zi No. 0002, ordering: 1. Changzhou Huasheng Pharmaceutical Co., Ltd. to compensate Eli Lilly and Company for economic losses and reasonable expenses incurred to stop the infringement, totaling RMB 3.5 million; and 2. rejection of Eli Lilly and Company's other claims. The case acceptance fee was RMB 809,744, of which Eli Lilly and Company bore RMB 161,950 and Changzhou Huasheng Pharmaceutical Co., Ltd. bore RMB 647,794. Eli Lilly and Company and Changzhou Huasheng Pharmaceutical Co., Ltd. were both dissatisfied and appealed. On May 31, 2016, the Supreme People's Court rendered Civil Judgment No. (2015) Min San Zhong Zi No. 1, ordering: 1. revocation of Civil Judgment No. (2013) Su Min Chu Zi No. 0002 of the Jiangsu Higher People's Court; and 2. rejection of Eli Lilly and Company's claims. The first- and second-instance case acceptance fees were RMB 809,744 each, of which Eli Lilly and Company bore RMB 323,897 and Changzhou Huasheng Pharmaceutical Co., Ltd. bore RMB 1,295,591.

Reasoning

The court in its effective judgment held that Article 7 of the Interpretation of the Supreme People's Court on Several Issues Concerning the Application of Law in the Trial of Patent Infringement Dispute Cases provides: "When the people's court determines whether the alleged infringing technical solution falls within the protection scope of a patent right, it shall examine all technical features recorded in the claim asserted by the right holder. Where the alleged infringing technical solution includes technical features identical or

equivalent to all technical features recorded in the claim, the people's court shall determine that it falls within the protection scope of the patent right; where the alleged infringing technical solution lacks one or more technical features recorded in the claim compared with all technical features recorded in the claim, or has one or more technical features that are neither identical nor equivalent, the people's court shall determine that it does not fall within the protection scope of the patent right." In this case, the drug allegedly produced and sold by Huasheng Company was the same as the product prepared by the patented process in question, both being olanzapine. Determining whether Huasheng Company's olanzapine preparation process fell within the protection scope of the patent right in question involved the following three issues.

I. On the protection scope of the patent right in question

Article 56(1) of the Patent Law provides: "The protection scope of an invention or utility model patent right shall be determined by the content of its claims, and the description and drawings may be used to interpret the claims." In this case, Eli Lilly sought protection of method (a) of claim 1 of the patent in question. That claim was drafted in an open-ended manner, in which only the tricyclic reduced product and N-methylpiperazine participating in the substitution reaction and the group being substituted were defined. Its protection scope covered all preparation processes that adopted the tricyclic reduced product and N-methylpiperazine to undergo a substitution reaction at the Q group to generate olanzapine, regardless of the reaction starting materials, solvents, or reaction conditions adopted. Based on this, the key to determining whether Huasheng Company's olanzapine preparation process fell within the protection scope of the patent right in question lay in the comparison of the reaction routes of the two technical solutions, while the specific reaction starting materials, solvents, reaction conditions, and so on were not included in the infringement comparison scope. Otherwise, the protection scope of the patent right in question would be improperly narrowed, harming Eli Lilly's lawful rights and interests.

II. On the olanzapine preparation process actually used by Huasheng Company

Article 57(2) of the Patent Law provides: "Where a patent infringement dispute involves an invention patent for a process of manufacturing a new product, the entity or individual manufacturing the identical product shall provide proof that its product manufacturing process is different from the patented process." In this case, the two parties had no objection that olanzapine was a new product as referred to in the Patent Law, and Huasheng Company should bear the burden of proving that its olanzapine preparation process was different from the patented process in question. Specifically, Huasheng Company should provide evidence proving that the reaction route of the olanzapine preparation process it actually used did not fall within the protection scope of the patent right in question; otherwise, it would bear the legal consequence of the presumption that Eli Lilly's infringement allegation was established due to its failure to provide proof.

In this case, Huasheng Company claimed that it had, from 2003 to the present, always used the process additionally filed with the SDA in 2008 to produce olanzapine, and submitted its 2003 and 2008 olanzapine batch production records (supplementary evidence 6 of the first instance), the 2003, 2007, and 2013 production regulations (supplementary evidence 7 of the first instance), the "Drug Supplementary Application Approval" (supplementary evidence 12 of the first instance), and other evidence to prove the olanzapine preparation process it actually used. As described above, the key to infringement determination in this case lay in the comparison of the reaction routes of the two technical solutions. The reaction route of Huasheng Company's 2008 additionally filed process can be seen in the "Olanzapine Drug Supplementary Application Registration Materials" submitted by it to the SDA, in which the 5.1.2 "process route" diagram under 5.1 "Research Materials and Literature on the Production Process of the Bulk Drug" showed the reaction route as: first protecting the secondary amino group in the "secondary amine compound" with a benzyl group to obtain the "benzyl compound" (benzylation), then conducting a ring-closure reaction to generate the "benzyl-substituted thienobenzodiazepine" tricyclic compound (reduced product). The amino group in the "reduced product" was substituted by N-methylpiperazine to generate the "condensate," and then the benzyl group was removed to obtain olanzapine. This court held that the existing evidence in the case could form a

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complete chain of evidence proving that Huasheng Company had, from 2003 to the expiration date of the patent right in question, always used the reaction route of its 2008 additionally filed process to produce olanzapine. The main reasons were as follows.

First, Huasheng Company applied to the SDA in 2008 for supplementary registration of the olanzapine drug, and in the "Olanzapine Drug Supplementary Application Registration Materials" it submitted, it expressly recorded the reaction route of its olanzapine preparation process. In response to that supplementary application, the Jiangsu Provincial drug regulatory department conducted production on-site inspection and product sampling of Huasheng Company on July 7 and August 25, 2009, and issued the "Drug Registration Production On-site Inspection Report" (acceptance number CXHB0800159), which showed that Huasheng Company's "production process was carried out according to the reported process," and that the three batches of samples had "been sampled according to the sampling requirements," with the on-site inspection conclusion of "passed." That is, Huasheng Company's 2008 additionally filed process had undergone on-site inspection by the drug regulatory department and was feasible. Based on this, on September 8, 2010, the SDA issued Huasheng Company the "Drug Supplementary Application Approval," approving Huasheng Company's olanzapine "change of production process and revision of quality standard." With respect to the feasibility of Huasheng Company's 2008 additionally filed process, Eli Lilly's expert assistant acknowledged it at the second-instance hearing, and the "Technical Appraisal Report" No. (2014) Si Jian Zi No. 02 issued by the Jiangsu Science and Technology Consulting Center also held in its appraisal conclusion that "the olanzapine preparation process filed by Huasheng Company with the SDA in 2008 is feasible." Therefore, in the absence of other contrary evidence, it should be presumed that Huasheng Company's 2008 additionally filed process was the olanzapine preparation process it actually used after obtaining the "Drug Supplementary Application Approval."

Second, generally speaking, a drug preparation process suitable for large-scale industrial production has cumbersome steps and complex operations, and its formation cannot be accomplished overnight. From the research and development stage to the actual production stage, its long-term technical accumulation process usually continuously optimizes and adjusts reaction conditions and operational details in response to defects found in actual production while maintaining a stable basic reaction route. Huasheng Company's olanzapine preparation process was acquired from IMM, and the two parties signed a "Technology Transfer Contract" on October 28, 1999. According to the contract, IMM was responsible for completing the pre-clinical approval materials and applying for clinical trials in Beijing. In the "New Drug Clinical Research Application Form" No. (Jing 99) Yao Shen Lin Zi No. 82 filled out by IMM in October 1999, the reaction route drawn in the "preparation process" column showed that it adopted the same reaction route as Huasheng Company's 2008 additionally filed process. In response to that new drug clinical research application, on November 9, 1999, the Beijing Municipal Health Bureau issued the "On-site Examination Report Form for New Drug Development," confirming that "the original records and experimental materials are basically complete and the content is true." On this basis, IMM and Huasheng Company, in accordance with the "Technology Transfer Contract," jointly submitted the new drug certificate and production application form (No. (2001) Jing Shen Chan Zi No. 019) to the SDA. In response to that application, on October 22, 2001, the Jiangsu Provincial Drug Administration issued the "On-site Examination Report Form for New Drug Development," confirming that "the original records of sample preparation and testing are basically complete." After a series of examinations including the foregoing on-site examinations, on May 9, 2003, IMM and Huasheng Company obtained the "New Drug Certificates" for olanzapine bulk drug and olanzapine tablets issued by the SDA. It can thus be seen that Huasheng Company had, since 1999, possessed an olanzapine preparation process with the same reaction route as its 2008 additionally filed process, and used it to apply for new drug registration and obtained the new drug certificate. Therefore, it was unlikely that Huasheng Company had used a completely different reaction route to produce olanzapine before its 2008 additionally filed process.

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Finally, the "approval conclusion" column of the "Drug Supplementary Application Approval" issued to Huasheng Company by the SDA on September 8, 2010, recorded: "The changed production process, without changing the original synthesis route, only adjusts the solvents and reagents used in the preparation process," that is, the SDA confirmed that Huasheng Company's 2008 additionally filed process had the same reaction route as its previous preparation process. Huasheng Company submitted in the first instance its 2003, 2007, and 2013 production regulations and the 2003 and 2008 olanzapine batch production records. Huasheng Company claimed that the above evidence involved its trade secrets, and the court of first instance organized the two parties to conduct closed cross-examination, confirming their authenticity and relevance. Upon review by this court, Huasheng Company's 2003 and 2008 olanzapine batch production records were records of actual production made respectively according to the 2003 and 2007 production regulations, and the above production regulations and batch production records all showed that the basic reaction route of Huasheng Company's olanzapine preparation process was the same as the reaction route of its 2008 additionally filed process, except that production details such as reaction conditions and solvents were adjusted on the basis of maintaining the unchanged basic reaction route, and continuously optimized. Such a technical accumulation process conforms to the laws of actual production.

In summary, this court held that Huasheng Company's 2008 additionally filed process was true and feasible, and that from 2003 to the expiration date of the patent right in question, Huasheng Company had always used the reaction route of the 2008 additionally filed process to produce olanzapine.

III. On whether Eli Lilly's infringement allegation was established

Comparing the reaction route of Huasheng Company's olanzapine preparation process with the process patent in question, the difference between the two lay in the different reaction steps and different key intermediates. Specifically, the amino group of the tricyclic reduced product used in Huasheng Company's olanzapine preparation process was protected by a benzyl group, so a benzylation reaction step necessarily existed before the substitution reaction to generate the benzylated tricyclic reduced product, and correspondingly a debenzylation reaction step necessarily existed after the substitution reaction to obtain olanzapine. In contrast, the reaction route of the patent in question did not protect the amino group in the tricyclic reduced product with a benzyl group, so there were no corresponding benzylation reaction step and benzyl-removal reaction step.

Article 17(2) of the Several Provisions of the Supreme People's Court on Issues Concerning the Application of Law in the Trial of Patent Dispute Cases provides: "Equivalent features refer to features that use substantially the same means to realize substantially the same function and achieve substantially the same effect, and that a person of ordinary skill in the art could, without creative labor, associate with the recorded technical features at the time the alleged infringement occurred." In this case, with respect to the difference between the reaction route of Huasheng Company's olanzapine preparation process and the process patent in question, first, the benzyl-protected tricyclic reduced product intermediate and the non-benzyl-protected tricyclic reduced product intermediate are different compounds, and there are differences in their chemical reaction properties. That is, on the non-benzyl-protected tricyclic reduced product intermediate, both the leaving Q group and the amino group can react with N-methylpiperazine, whereas on the benzyl-protected tricyclic reduced product intermediate, because the amino group therein is protected by a benzyl group, it cannot undergo an undesired substitution reaction with N-methylpiperazine, and the substitution reaction can only occur at the Q group. Correspondingly, the process of the patent in question has no benzylation and debenzylation reaction steps before and after the substitution reaction. Therefore, the two technical solutions differ considerably in reaction intermediates and reaction steps. Second, due to the addition of benzylation and debenzylation steps, Huasheng Company's olanzapine preparation process would suffer some loss in the yield of the final product, whereas the patent in question, having no benzylation protection step and debenzylation step, would not suffer a corresponding decrease in yield. Therefore, the two technical solutions differ considerably in technical effects such as yield. Finally, although benzyl-protecting the amino

group in the tricyclic reduced product to reduce side reactions is common knowledge in the field of chemical synthesis, this change is substantive: the reaction properties of the benzyl-protected tricyclic reduced product intermediate changed, and the addition of reaction steps also reduced the yield. Moreover, the fact that benzyl protection is common knowledge only indicates that Huasheng Company's olanzapine preparation process was a limited improvement relative to the patented process, but does not mean that the technical means adopted by the two were substantially the same.

In summary, Huasheng Company's olanzapine preparation process differed from the patented process in question in whether the tricyclic reduced product intermediate was a benzylated intermediate and in the benzylation and debenzylation steps added as a result. The corresponding technical features did not constitute substantially the same technical means, and the technical effects achieved differed considerably, and thus did not constitute equivalent features. Therefore, Huasheng Company's olanzapine preparation process did not fall within the protection scope of the patent right in question.

In summary, Huasheng Company's olanzapine preparation process did not fall within the protection scope of the patent right in question owned by Eli Lilly, and the first-instance judgment erred in the determination of facts and application of law, and was corrected in accordance with the law.

(Judges of the effective judgment: Zhou Xiang, Wu Rong, Song Shuhua)

Relevant Legal Provisions

Article 59(1), Article 61, and Article 68(1) of the Patent Law of the People's Republic of China (2008 Amendment) (this case applied Article 56(1), Article 57(2), and Article 62(1) of the Patent Law of the People's Republic of China as amended in 2000)

Articles 78 and 79 of the Civil Procedure Law of the People's Republic of China

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