Recent Development on Chinese Judiciary System & Cases in Pharmaceutical Field

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SBZL IP LAW OFFICE

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01 Recent Development on Chinese Judiciary System

Decision of the Standing Committee of the National People's Congress on Several Issues Concerning Litigation Procedures of Patent and Other Intellectual Property Cases

(Adopted by the Standing Committee of the Thirteenth National People's Congress at the 6th Conference on October 26, 2018)

Article 1

If the parties are not satisfied with the judgement or ruling of the first instance of an intellectual property civil case that involves more technical issues, such as patents for invention, patents for utility model, new varieties of plants, layout designs of integrated circuits, know-how, computer software, monopoly and so on, they shall appeal to the Supreme People's Court.

Article 2

If the parties are not satisfied with the judgement or ruling of the first instance of an intellectual property administrative case that involves more technical issues, such as patents, new varieties of plants, layout designs of integrated circuits, know-how, computer software, monopoly and so on, they shall appeal to the Supreme People's Court.

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Decision of the Standing Committee of the National People's Congress on Several Issues Concerning Litigation Procedures of Patent and Other Intellectual Property Cases

(Adopted by the Standing Committee of the Thirteenth National People's Congress at the 6th Conference on October 26, 2018)

Article 3

For the judgement, ruling, or mediation decision of the first instance of the above identified cases, that has already come into effect, when the application for retrial or protest is filed according to the trial supervision procedure, they shall be heard by the Supreme People's Court. The Supreme People's Court may also designate a lower People's Court to conduct a retrial according to the law.

Article 5

This decision shall become effective since January 1, 2019.

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Provisions of the Supreme People's Court on Several Issues concerning Intellectual Property Court

(Adopted by the Supreme People's Court's Judicial Committee at the 1756th Conference on December 3, 2018)

Article 2

The Intellectual Property Court hears the following cases:

(1) appeals against civil judgements or rulings of first instance made by High People's Courts, Intellectual Property Courts, or Intermediate People's Courts in connection with patents for invention, patents for utility model , new varieties of plants, layout designs of integrated circuit, know-how, computer software and monopoly;

(2) appeals against administrative judgements or rulings of first instance made by Beijing Intellectual Property Court on authorization and determination in connection with patents for invention, patents for utility model, patents for design, new varieties of plants, and layout designs of integrated circuit;

(3) appeals against administrative judgements or rulings of first instance made by High People's Courts, Intellectual Property Courts, or Intermediate People's Courts on administrative punishments and the like in connection with patents for invention, patents for utility model, patents for design, new varieties of plants, layout designs of integrated circuit, know-how, computer software, and monopoly;

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Provisions of the Supreme People's Court on Several Issues concerning Intellectual Property Court

(Adopted by the Supreme People's Court's Judicial Committee at the 1756th Conference on December 3, 2018)

(4) major and complicated civil and administrative cases of first-instance as referred to in items (1), (2) and (3) of this Article;

(5) cases in connection with applications for retrial, protest, retrial and the like, if any, lodged pursuant to the law against the binding first instance judgements, rulings and mediation decisions as referred to in items (1), (2) and (3) under the trial supervision procedures;

(6) cases concerning jurisdiction disputes of first instance, applications for reconsiderations for decisions of compensation and detention, requests for extension of trial period, and the like as referred to in items (1), (2) and (3) of this Article;

(7) other cases that the Supreme People's Court considers should be tried by the Intellectual Property Court.

Article 15

The Provisions shall come into force on January 1, 2019. Where the judicial interpretations previously issued by the Supreme People's Court are inconsistent with these Provisions, the Provisions shall prevail.

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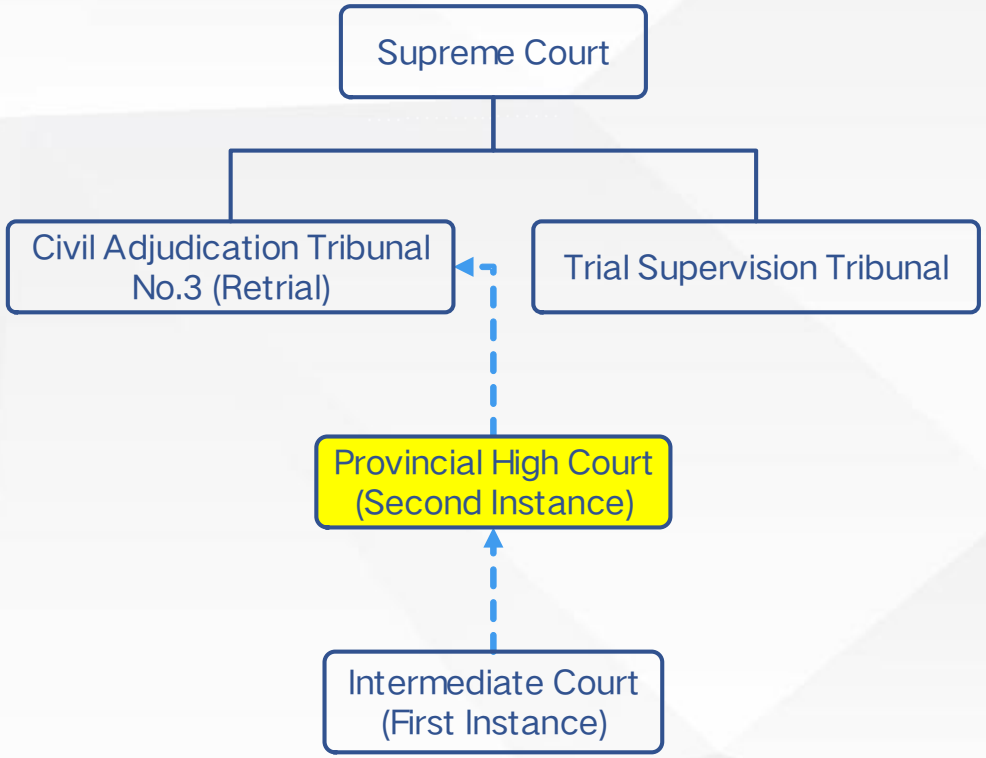
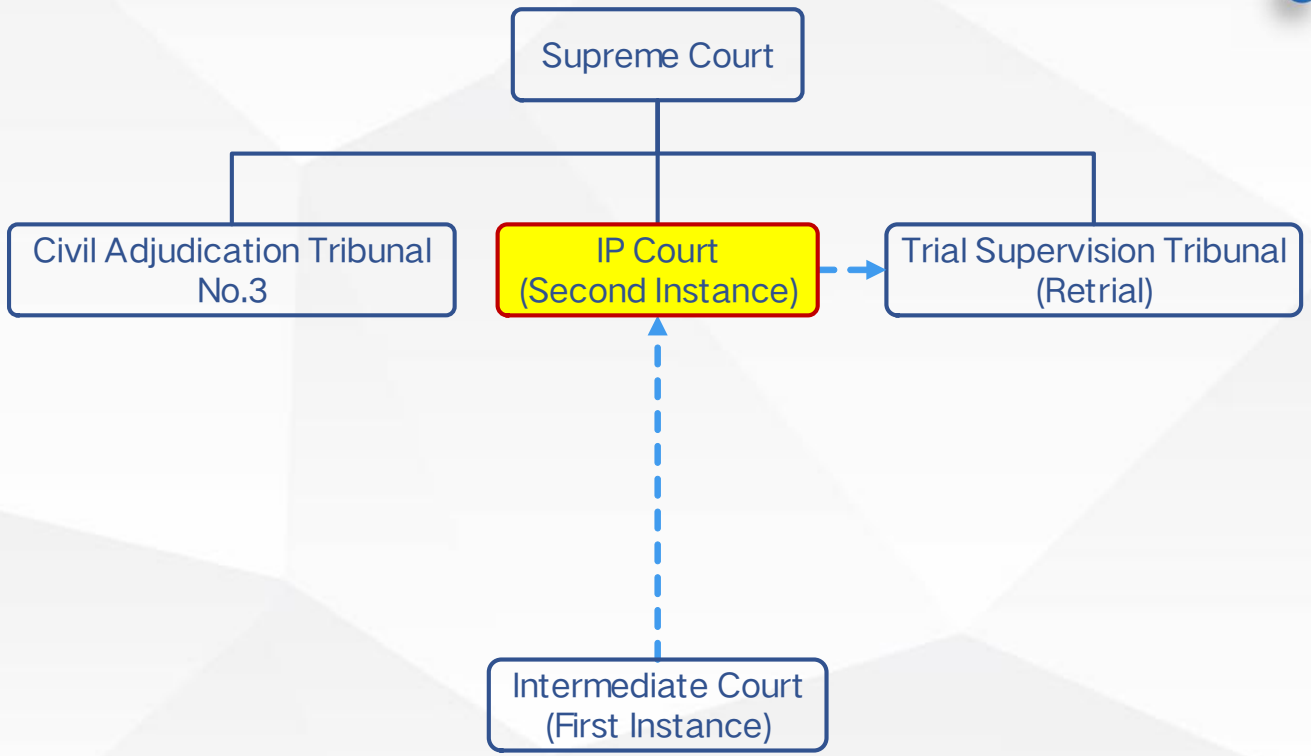


Before January 1, 2019



As of January 1, 2019

CIVIL CASES

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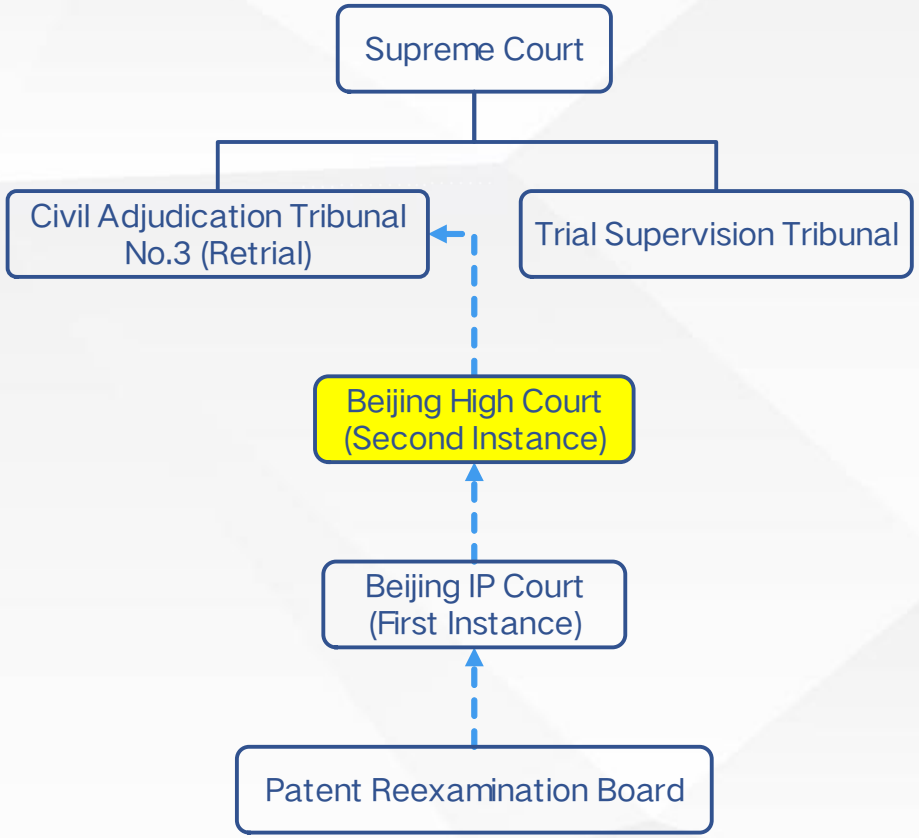
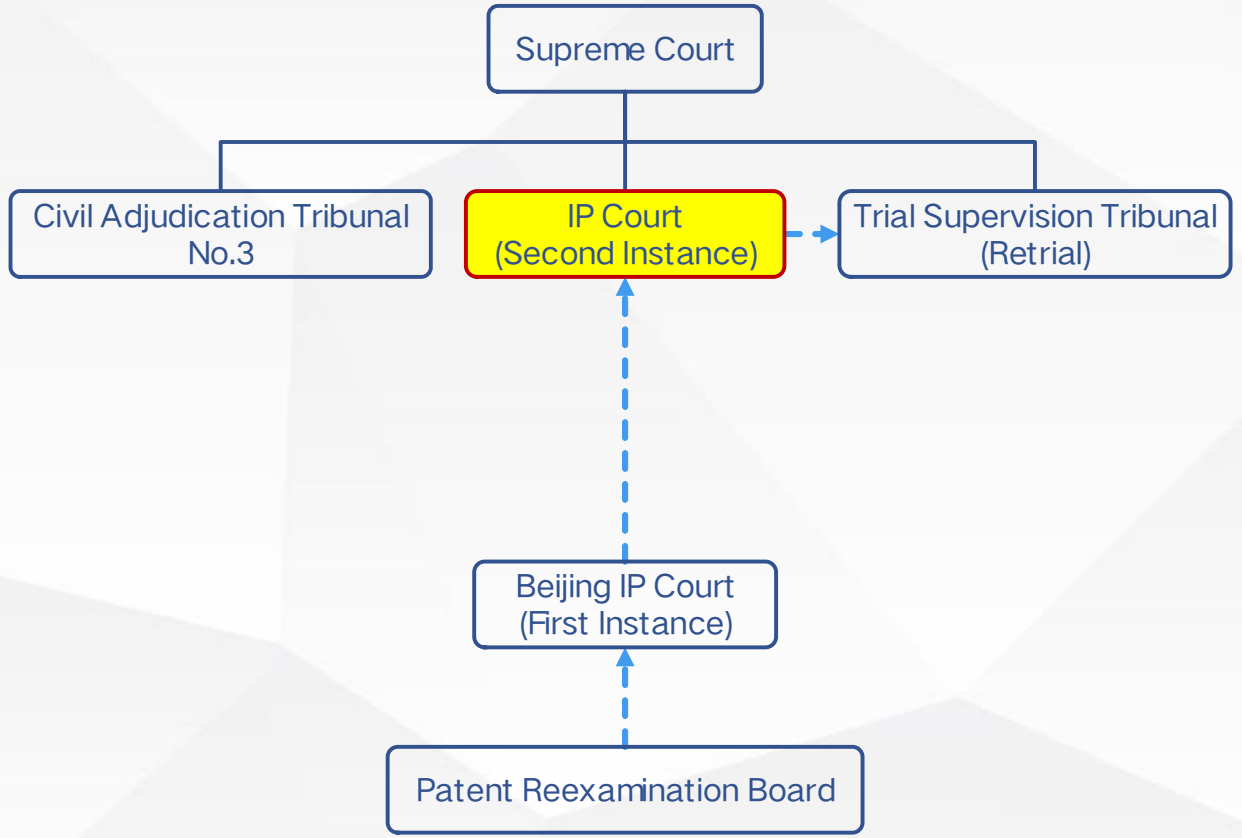


Before January 1, 2019



As of January 1, 2019

ADMINISTRATIVE CASES

01 Recent Development on Chinese Judiciary System

Intellectual Property Court of Supreme People's Court		
Beijing	Beijing High Court	Beijing Intellectual Property Court
Tianjin	Tianjin High Court	Tianjin Intellectual Property Court*
Hebei	Hebei High Court	Shijiazhuang Intermediate Court
Shanxi	Shanxi High Court	Taiyuan Intermediate Court
Inner Mongolia	Inner Mongolia Autonomous Region High Court	Huhhot Intermediate Court Baotou Intermediate Court
Liaoning	Liaoning High Court	Shenyang Intermediate Court Dalian Intermediate Court
Jilin	Jilin High Court	Changchun Intellectual Property Court*
Heilongjiang	Heilongjiang High Court	Harbin Intermediate Court Qiqihar Intermediate Court
Shanghai	Shanghai High Court	Shanghai Intellectual Property Court
Jiangsu	Jiangsu High Court	Nanjing Intellectual Property Court* Suzhou Intellectual Property Court*
Zhejiang	Zhejiang High Court	Hangzhou Intellectual Property Court* Ningbo Intellectual Property Court*
Anhui	Anhui High Court	Hefei Intellectual Property Court*

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Intellectual Property Court of Supreme People's Court		
Fujian	Fujian High Court	Fuzhou Intellectual Property Court*
Jiangxi	Jiangxi High Court	Nanchang Intellectual Property Court*
Shandong	Shandong High Court	Jinan Intellectual Property Court* Qingdao Intellectual Property Court*
Henan	Henan High Court	Zhengzhou Intellectual Property Court*
Hubei	Hubei High Court	Wuhan Intellectual Property Court*
Hunan	Hunan High Court	Changsha Intellectual Property Court*
Guangdong	Guangdong High Court	Guangzhou Intellectual Property Court Shenzhen Intellectual Property Court*
Guangxi	Guangxi Zhuang Autonomous Region High Court	Nanning Intermediate Court Liuzhou Intermediate Court
Hainan	Hainan High Court	Haikou Intermediate Court
Chongqing	Chongqing High Court	Chongqing No 1 Intermediate Court Chongqing No 5 Intermediate Court
Sichuan	Sichuan High Court	Chengdu Intellectual Property Court*
Guizhou	Guizhou High Court	Guiyang Intermediate Court Zunyi Intermediate Court

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Intellectual Property Court of Supreme People's Court

Yunnan	Yunnan High Court	Kunming Intermediate Court
Tibet	Tibet Autonomous Region High Court	Lhasa Intermediate Court
Shaanxi	Shaanxi High Court	Xian Intellectual Property Court*
Gansu	Gansu High Court	Lanzhou Intellectual Property Court*
Qinghai	Qinghai High Court	Xining Intermediate Court
Ningxia	Ningxia Hui Autonomous Region High Court	Yinchuan Intermediate Court
Xinjiang	Xinjiang Uygur Autonomous Region High Court	Urumqi Intellectual Property Court*
	Production and Construction Corps Branch of Xinjiang Uygur Autonomous Region High Court	Intermediate Court of the Eighth Division of Xinjiang Production and Construction Corps Intermediate Court of the Twelfth Division of Xinjiang Production and Construction Corps

Note: Intellectual Property Courts with * are divisions of intermediate courts, enjoying trans-administrative regional jurisdiction of technology related intellectual property cases, such as patent cases.

Source: Intellectual Property Court of Supreme People's Court
http://ipc.court.gov.cn/en-us/news/more-2-10.html

01 Recent Development on Chinese Judiciary System

The Intellectual Property Court of the Supreme Court is a standing judicial organ of the Supreme Court located in Beijing, which primarily hears cases on appeal over patent and other intellectual property rights involving professional technologies throughout the country. This Court aims to further unify the trial criteria of intellectual property cases, protect the legitimate rights and interests of various market entities lawfully and equally, strengthen the protection over intellectual property rights, optimize the law-based environment for scientific and technological innovation, and accelerate the implementation of the Innovation-driven Development Strategy ultimately.

02

Important Cases in Pharmaceutical Field

02 Important Cases in Pharmaceutical Field

Case I:
Amendments to Markush Claim during Invalidation Proceedings

Case II:
Issues on Supplementary Experimental Data in Chemical and Medicinal Fields

Case III:
Issues on Inventive Step of Pharmaceutical Compounds

Case IV:
Preliminary Injunction

02 Important Cases in Pharmaceutical Field

Case I: Amendments to Markush Claim during Invalidation Proceedings

PRB vs. Winsunnyharmony (patentee: Daiichi Sankyo) (2016) ZGFXZ No. 41

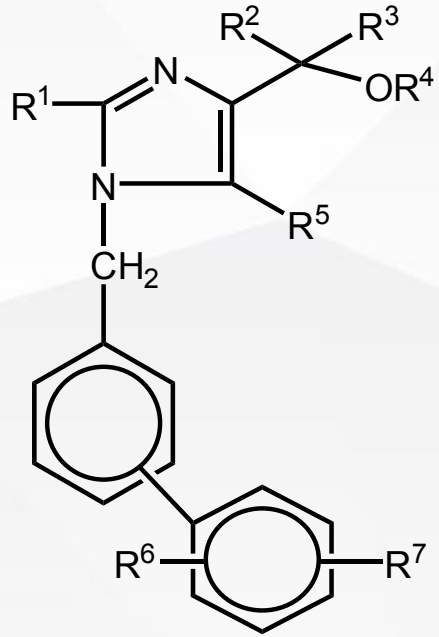
国家知识产权局 专利复审委员会 PATENT REEXAMINATION BOARD OF SIPO

万生力合 WINSUNNY

Daiichi-Sankyo

Claims:

1. A process for preparing a pharmaceutical composition for the treatment and prophylaxis of hypertension, comprising mixing an anti-hypertension agent with a pharmaceutically acceptable carrier or diluent, wherein the anti-hypertension agent is at least one of the compounds of formula (I) or pharmaceutically acceptable salts and esters thereof,



02 Important Cases in Pharmaceutical Field

R^1 represents an alkyl group having from 1 to 6 carbon atoms;
R^2 and R^3 are same or different and independently represent alkyl groups having from 1 to 6 carbon atoms;
R^4 represents a hydrogen atom; or an alkyl group having from 1 to 6 carbon atoms;
R^5 represents a carboxy group, a group of formula $-COOR^{5a}$ or a group of formula $-CONR^8R^9$,

wherein R^8 and R^9 are same or different and independently selected from the group consisting of hydrogen atoms, an unsubstituted alkyl group having from 1 to 6 carbon atoms; an alkyl group having from 1 to 6 carbon atoms substituted with a carboxy group or a alkoxycarbonyl group in which the alkyl part has from 1 to 6 carbon atoms; or

R^8 and R^9 together represent a substituted alkylene group which has from 2 to 6 carbon atoms and which is substituted by one alkoxycarbonyl groups in which the alkyl part has from 1 to 6 carbon atoms; and

wherein R^{5a} represents an alkyl group having from 1 to 6 carbon atoms; an alkanoyloxyalkyl group, in which the alkanoyl part and the alkyl part independently have from 1 to 6 carbon atoms; an alkoxycarbonyloxyalkyl group, in which the alkoxy part and the alkyl part independently have from 1 to 6 carbon atoms; a (5-methyl-2-oxo-1,3-dioxolen-4-yl)methyl group; or a phthalidyl group;
R^6 represents a hydrogen atom; and
R^7 represents a carboxy group or a tetrazol-5-yl group.

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R^1 represents an alkyl group having from 1 to 6 carbon atoms;
R^2 and R^3 are same or different and independently represent alkyl groups having from 1 to 6 carbon atoms;
R^4 represents a hydrogen atom; or an alkyl group having from 1 to 6 carbon atoms;
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wherein R^8 and R^9 are same or different and independently selected from the group consisting of hydrogen atoms, an unsubstituted alkyl group having from 1 to 6 carbon atoms; an alkyl group having from 1 to 6 carbon atoms substituted with a carboxy group or a alkoxycarbonyl group in which the alkyl part has from 1 to 6 carbon atoms; or

R^8 and R^9 together represent a substituted alkylene group which has from 2 to 6 carbon atoms and which is substituted by one alkoxycarbonyl groups in which the alkyl part has from 1 to 6 carbon atoms; and

wherein R^{5a} represents an alkyl group having from 1 to 6 carbon atoms; an alkanoyloxyalkyl group, in which the alkanoyl part and the alkyl part independently have from 1 to 6 carbon atoms; an alkoxycarbonyloxyalkyl group, in which the alkoxy part and the alkyl part independently have from 1 to 6 carbon atoms; a (5-methyl-2-oxo-1,3-dioxolen-4-yl)methyl group; or a phthalidyl group;
R^6 represents a hydrogen atom; and
R^7 represents a carboxy group or a tetrazol-5-yl group.

02 Important Cases in Pharmaceutical Field

PRB: A granted Markush claim belongs to an entire technical solution. A technical feature is not allowed to be deleted from the claim.

Beijing First Intermediate Court (First Instance): Deletion of a Markush element from a Markush claim is not directly equivalent to deletion of a parallel technical solution.

Beijing High Court (Second Instance): The applicant or patentee is allowed to delete any element in any variable either during the examination on the merits and reexamination proceedings or during the invalidation proceedings. Such deletion belongs to deletion of a technical solution.

02 Important Cases in Pharmaceutical Field

Supreme Court (Retrial):

◇A Markush claim must be considered as a general combination technical solution, no matter how many variants an combinations the claim contains.

◇A Markush claim must be considered as a set of Markush elements, rather than a set of numerous compounds. A Markush element can represent a single compound under specific circumstances, however in general, a Markush element should be understood as a sort of compounds with common properties and functions.

◇An amendment to a Markush claim must be strictly limited during the invalidation proceedings. The principle of allowing an amendment to a Markush claim should be no sort of compounds or individual compound with new properties and effects is presented due to the amendment. However, individual case factors should be fully considered as well. If the applicant or patentee is allowed to delete any element in any variable, even if the deletion narrows the scope of protection of claims, which will not harm the interests of the public, because of the uncertainty of whether the new scope of protection will arise, it is not only impossible to give the public a stable expectation, but also unfavorable to maintain the stability of the patent invalidation system.

02 Important Cases in Pharmaceutical Field

Case II: Issues on Supplementary Experimental Data in Chemical and Medicinal Fields

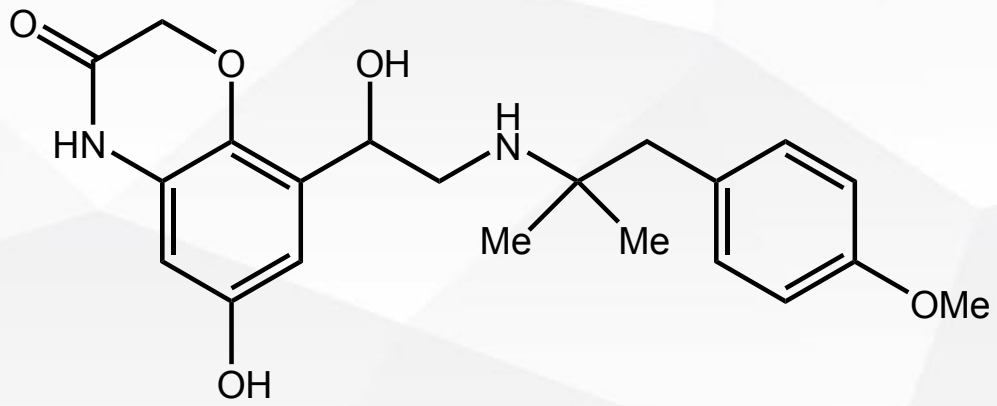
Boehringer Ingelheim Pharma vs. PRB (2017) JXZ No. 3688

Boehringer Ingelheim

国家知识产权局 专利复审委员会 PATENT REEXAMINATION BOARD OF SIPO

Claims:

1. Compound of formula 1a:



02 Important Cases in Pharmaceutical Field

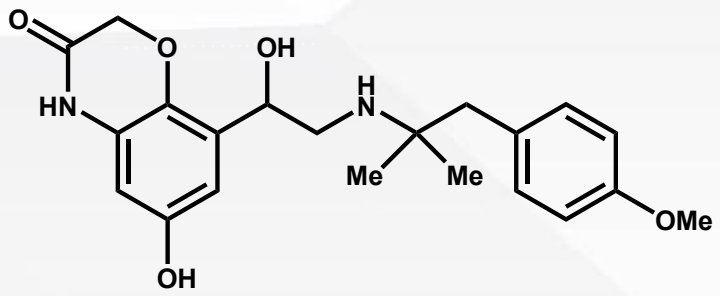
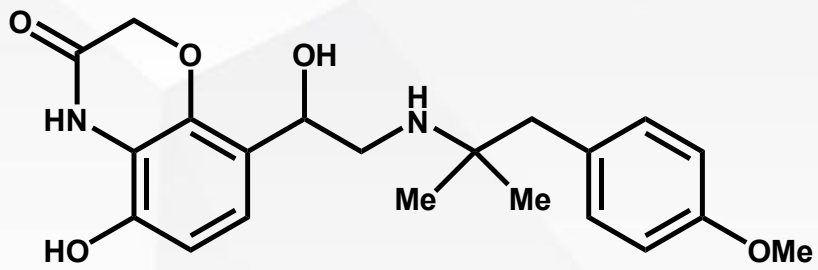
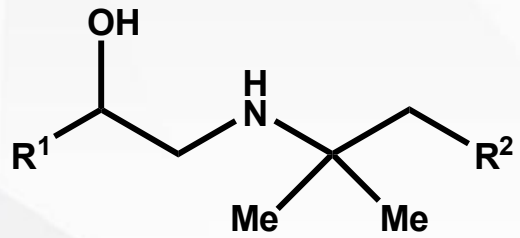
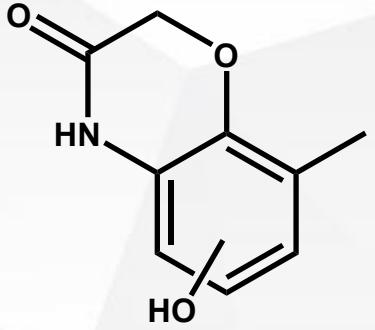
Specification:

1. The aim of the present invention is therefore to provide betamimetics which have a therapeutic benefit in the treatment of COPD and are characterized by a longer duration of activity and can thus be used to prepare pharmaceutical compositions with a longer duration of activity.

2. Compounds were prepared in Examples 1-35.

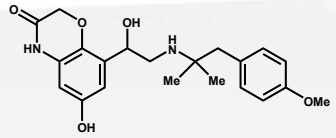
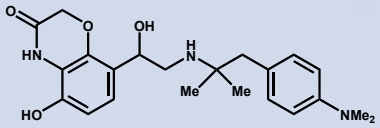
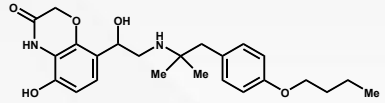
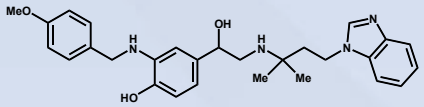
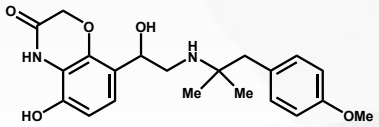
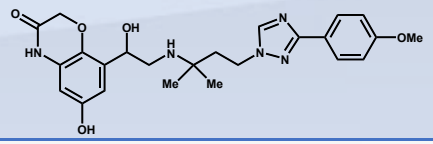
3. No data of effects were described.

02 Important Cases in Pharmaceutical Field

Claim 1	D1 (US 2002/0022625 A1), Example 4
	
	
	wherein R^1 is 

02 Important Cases in Pharmaceutical Field

Supplementary Experimental Data

#	Structure	β1 IA[%]	β1 EC_{50}[nM]	β2 IA[%]	β2 EC_{50}[nM]	EC_{50}(β1)/EC_{50}(β2)
1a		7	358	53	1.4	256
D1.1		99	8.5	56	2.0	4.3
D1.2		90	10.2	130	1.1	9.3
D1.3		47	223	49	19.5	11.4
D1.4		93	0.7	115	0.6	1.0
D1.5		24	7.2	54	1.4	5.1

Applicant's Conclusion: The compound of formula 1a is a very potent partial agonist of human β2 receptor and has excellent selectivity relative to β1 receptor. [EC_{50}(β1)/EC_{50}(β2)]

02 Important Cases in Pharmaceutical Field

PRB Decision:

(1) The technical effect to be demonstrated by the supplementary experimental data is the compound of formula 1a has excellent β2 receptor agonist activity relative to β1 receptor.

(2) The technical effect described in the specification is it is anticipated that the compound of formula 1a has betamimetics activity and therefore can be used to treat COPD. However, the technical effect has not been confirmed.

(3) Where the applicant does not recognize the technical effect or describe the technical effect in the original application documents on the filing date, the supplementary experimental evidence, which is submitted after the filing date to demonstrate the technical effect that is found later, does not belong to the disclosure of the original application. Furthermore, prior to the filing date, one skilled in the art cannot learn the compounds having such structures would have had high $EC_{50}(\beta1)/EC_{50}(\beta2)$ selectivity.

In view of the above, based on these experimental data, it is unfair for the public to conclude that the technical solution can achieve the technical effect or performance and then involves an inventive step, which violates the principle of first-to-file system.

Beijing Intellectual Property Court and Beijing High Court: Affirmed the Decision.

02 Important Cases in Pharmaceutical Field

Conclusion: The technical contents for demonstrating the use and/or effects that should have been described in the specification is inadmissible by submitting supplementary experimental data after the filing date.

02 Important Cases in Pharmaceutical Field

Case III: Issues on Inventive Step of Pharmaceutical Compounds

AstraZeneca AB vs. PRB (Petitioner: SALUBRIS) (2018) JXZ No. 6345

AstraZeneca

国家知识产权局 专利复审委员会 PATENT REEXAMINATION BOARD OF SIPO

SALUBRIS 信立泰

Claims:

1. A compound or pharmaceutically acceptable salts thereof, the compound is: [1S-(1α,2α,3β(1S*,2R*),5β)]-3-[7-[2-(3,4-difluorophenyl)cyclopropyl]amino]-5-(propylthio)-3H-1,2,3-triazolo[4,5-d]pyrimidin-3-yl)-5-(2-hydroxyethoxy)-cyclopentane-1,2-diol.

Specification:

The present invention provides a P_{2T}-receptor antagonist.

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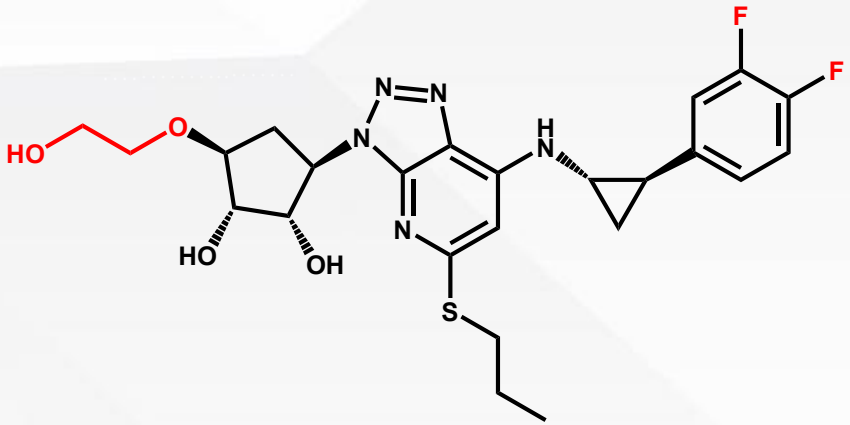
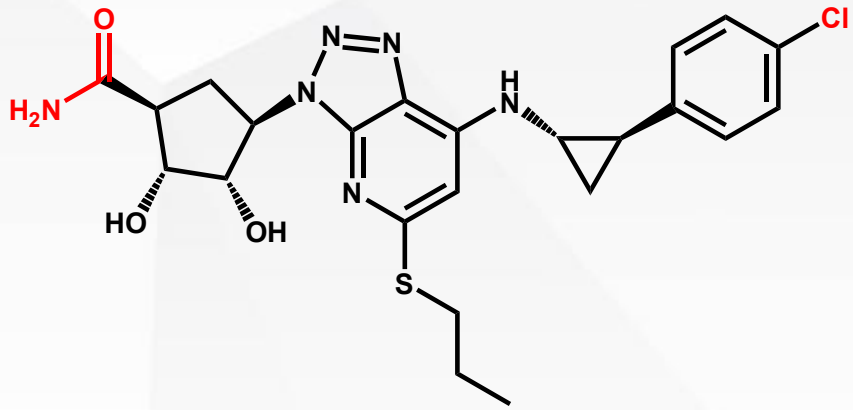
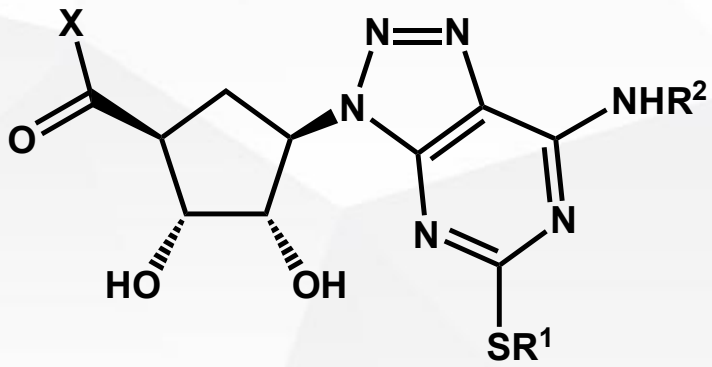
Important Cases in Pharmaceutical Field

Claim 1 (Ticagrelor)	D1 (WO 1998/028300 A1), Example 86
	
	 Claim 1 of D1

02 Important Cases in Pharmaceutical Field

The differences between Claim 1 and Example 86 of D1 are as follows:

(1) The substituents on the phenyl group of Claim 1 are 3,4-difluoro, while the substituent on the phenyl group of Example 86 of D1 is 4-chloro.

(2) The substituent on the cyclopentane of Claim 1 is $-OCH_2CH_2OH$, while the substituent on the cyclopentane of Example 86 of D1 is $-C(O)NH_2$.

PRB Decision:

(1) It is conventional for one skilled in the art to replace the substituents on the phenyl group with other halogen atoms (See Claim 1 of D1: the optional phenyl substituent being further optionally substituted by one or more halogen atoms).

(2) It is conventional technical means for one skilled in the art to modify the core of a compound in the compound design field regardless of the substituents $-CH_2OH$, $-OCH_2CH_2OH$, $-OH$, or $-C(O)NH_2$ (See Evidence 3, 4, 5 or 7 submitted by the petitioner).

Furthermore, no unexpected results are produced by such substitution.

02 Important Cases in Pharmaceutical Field

Beijing Intellectual Property Court (First Instance): Affirmed the Decision.

Beijing High Court (Second Instance):

(1) Both floro and chloro belong to the common halogen substituents. It is easy for one skilled in the art to choose one or more substituents.

(2) The compound in Example 86 of D1 must be learnt in view of the entire technical solution of D1. Claim 1 of D1 is a Markush claim. It is well-known that a Markush claim comprises an unvaried skeleton portion and variable Markush elements. In view of the entire technical solution of D1, the carbonyl group connected with the phenyl group belongs to the unvaried skeleton rather than modifiable and variable substituent. The PRB violates the common sense of one skilled in the art by bringing the carbonyl group which belongs to the the unvaried skeleton portion into variable substituents.

Therefore, reversed and remanded.

02 Important Cases in Pharmaceutical Field

Case IV: Preliminary Injunction

Shanghai Novartis Trading Co., Ltd. vs. Jiangsu Hansoh Pharmaceutical Co., Ltd. (2014) EZMB No. 07639

NOVARTIS

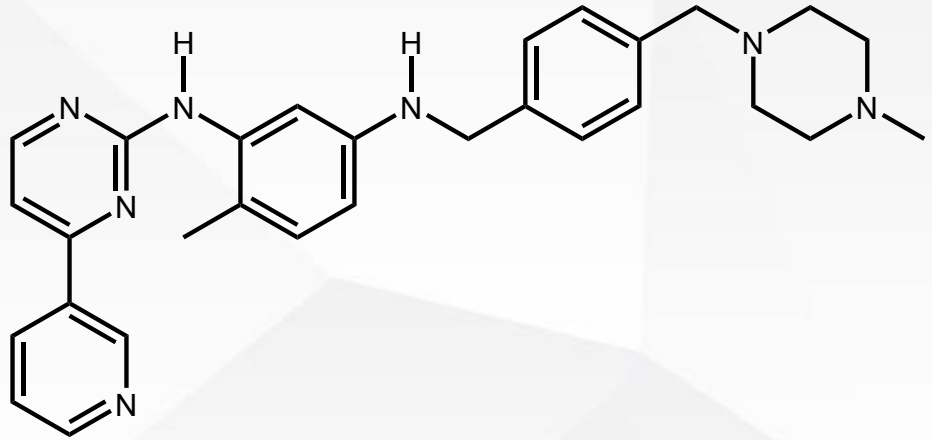
豪森药业 HANSOH PHARMA

The Beijing Second Intermediate People's Court issued on July 10, 2014 an Order in Shanghai Novartis Trading Co., Ltd. v. Jiangsu Hansoh Pharmaceutical Co., Ltd., granting Novartis' request for an injunction to prevent Hansoh from using the label containing the recitation "after administering the same dose (400 mg/day), the drug exposure of GIST patients at steady state is 1.5 fold of CML patients. In accordance with the preliminary pharmacokinetic studies of GIST patient population, changes of three parameters (albumin, WBC and bilirubin) in pharmacokinetics of imatinib have statistically significant effects. Low albumin level reduces clearance as higher WBC level does. However, these effects are insufficient to determine that the dose adjustment is needed." in the "pharmacokinetics" portion during manufacturing, selling and offering to sell "昕维"® imatinib mesylate, the generic version of Novartis's NDA drug GLIVEC®.

02 Important Cases in Pharmaceutical Field

Claims:

1. The use of 4-(4-methylpiperazin-1-ylmethyl)-N-[4-methyl-3-(4-pyridin-3-yl)pyrimidin-2-yl-amino)phenyl]-benzamide of the formula I



or a pharmaceutical acceptable salt thereof for the manufacture of pharmaceutical compositions for use in the treatment of gastrointestinal stromal tumours.

4-(4-methylpiperazin-1-ylmethyl)-N-[4-methyl-3-(4-pyridin-3-yl)pyrimidin-2-yl-amino)phenyl]-benzamide of the formula I is knownas imatinib.

02 Important Cases in Pharmaceutical Field

From this case, we can learn how to determine whether a preliminary injunction should be granted.

I. Plaintiff's Standing

◇ I Plaintiff should be the patentee or the interested party of the patent in suit. As to the interested party,

∅ An exclusive licensee has the standing to file a request for an injunction in its own name.

∅ A sole licensee has the standing to file a request for an injunction, where the licensor does not file such a request.

∅ A simple licensee has the standing to file a request for an injunction, where the licensor clearly allows the simple licensee to file such a request in its own name.

◇ The plaintiff should show the patent in suit is valid and in a steady state. Specifically,

∅ If the patent in suit is an invention, the plaintiff can provide the court with the prosecution history documents and invalidity proceedings documents, if any.

∅ If the patent in suit is a utility model or a design, the plaintiff can provide the court with a report on patentability issued by the China National Intellectual Property Administration (CNIPA).

02 Important Cases in Pharmaceutical Field

II. Possibility of Infringement

The purpose of a preliminary injunction is to promptly stop or prevent others from conducting infringement. Therefore, the existence of infringement is a key factor for the court to grant a preliminary injunction. In practice, the court will hold a hearing to compare the infringing product with the patent claims in suit. As the hearing is different from the trial, it would be sufficient by showing high possibility of infringement rather than inevitable establishment of infringement.

III. Irretrievable Damage to Plaintiff Caused by Infringement

The so-called "irretrievable" refers to that it is difficult to convert the damage into money so that the monetary compensation is not a sufficient remedy. The damage includes not only the property loss, but the loss of competitive advantages, market share, and goodwill. Therefore, the plaintiff should preliminarily demonstrate the plaintiff's damage caused by or the defendant's profits gained by the occurrence of infringement and the continuing occurrence of infringement.

02 Important Cases in Pharmaceutical Field

IV. Balance of Interests

◇ The balance of plaintiff's interests and defendant's interests should be considered.

The legal right should be protected, while whether the damage to the defendant caused by granting a preliminary injunction is greater than the damage to the plaintiff caused by not granting such an injunction should be considered. It should prevent the defendant's production and management from getting into trouble caused by an improper injunction.

◇ The balance of plaintiff's right and the public interests should be considered.

That is to say, whether the public interests would be harmed by granting a preliminary injunction should be considered. It should be noted although patent right belongs to private right, scenario that public interests possess considerable weights in some special cases such as pharmaceuticals occurs.

02 Important Cases in Pharmaceutical Field

V. Legitimate and Valid Bond

In general, it is difficult to determine the form and amount of bond for a preliminary injunction.

◇ Bank guarantee, guarantee of a third party and the like are acceptable.

◇ The amount of bond should be determined on account of damage possibly caused to the defendant, the bond capacity of the plaintiff and the like.

02 Important Cases in Pharmaceutical Field

Provisions of the Supreme People's Court on Several Issues Concerning the Application of Law in the Review of Act Preservation in Intellectual Property Disputes

(Adopted by the Supreme People's Court's Judicial Committee at the 1755th Conference on November 26, 2018)

Article 7

The people's court shall take the following factors into consideration in the examination of the application for act preservation:

(1) whether the applicant's request has a factual basis and a legal basis, including whether the claimed intellectual property right is stable;

(2) whether not taking act preservation measures will cause irreparable damage to the applicant's lawful rights and interests or cause the judgement of the case to be difficult to enforce;

(3) whether the damage caused to the applicant by not taking act preservation measures exceeds the damage caused to the respondent by taking the act preservation measures;

(4) whether taking act preservation measures harms the public interest; and

(5) other factors that should be considered.

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Q & A

THANK YOU FOR LISTENING

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