北京知识产权法院
涉医药专利典型案例

案例一：涉“玛巴洛沙韦前药”发明专利权无效行政纠纷案
——马库什化合物权利要求得到说明书支持的判断

1.基本案情

本专利系名称为“被取代的多环性氨基甲酰基吡啶酮衍生物的前药”的发明专利，专利权人为盐某某制药株式会社，本专利共9项权利要求，其中独立权利要求1涉及一种通式化合物、或其制药上可接受的盐。刘某某向国家知识产权局提出无效宣告请求，国家知识产权局作出被诉决定，维持本专利权有效。刘某某不服，向北京知识产权法院提起行政诉讼，主张本专利权利要求1的“三环”结构化合物的药物活性及制备方法均得不到说明书的支持，权利要求1涵盖了大量骨架结构差异巨大的三环化合物，而本专利说明书中仅公开6个三环化合物制备例以及1个三环化合物效果例，权利要求1的概括超出了说明书公开的范围，得不到说明书支持。北京知识产权法院经审理认为，本专利权利要求1中的三环结构化合物的药物活性和制备方法均能够得到说明书的支持，符合2009年《中华人民共和国专利法》（简称专利法）第二十六条第四款的规定，判决驳回原告刘某某的诉讼请求。判决作出后，各方当事人均未提起上诉，本案一审判决已生效。

2.典型意义

马库什化合物权利要求能否得到说明书的支持是药物化合物专利授权确权领域的难点问题，原因在于马库什权利要求本身的特殊性质与权利要求能否得到说明书支持的判断均涉及权利要求的概括，但具体标准有待厘清。本专利的发明目的是将在先发明中的化合物作为母体化合物进行前药化，涉及前药化合物能否得到说明书支持的判断，其中前体药物玛巴洛沙韦是盐某某制药株式会社首创的新作用机制的抗流感病毒新药，也是经国家药品监督管理局批准的治疗流感的首个也是唯一单剂量口服药物（商品名称“速福达”）。本案判决对于马库什权利要求的性质进行了界定。同时，厘清了马库什权利要求能否得到说明书支持的标准。对于日后涉及马库什权利要求的专利文件撰写提供了明确的规则指引，增强了专利效力的可预期性，有助于医药企业专利保护体系的有效构筑。

案例二：“宽胸理气口服液”专利申请驳回复审行政纠纷案
——中药组方发明专利创造性的判断规则

1.基本案情

本申请系名称为“宽胸理气口服液”的发明专利申请，申请人为某中医研究所。国家知识产权局作出复审决定：维持对本申请作出的驳回决定。某中医研究所不服该复审决定，向北京知识产权法院提起行政诉讼，主张被诉决定忽视本申请独特的病机、治则与君臣佐使组方结构，不能仅依据单味药材功效即认定技术方案容易想到，因此，本申请具备创造性。北京知识产权法院经审理认为，中药组合物创造性评判不能等同于单味药材功效简单叠加，应当立足本领域技术人员视角，从整体考察组方的病机认知、治法治则、君臣佐使配伍结构、药味取舍与用量配比。本申请与对比文件虽然存在部分相同药材，但二者核心病机认知、治疗思路不同，药物配伍体系发生重构，超出本领域技术人员在对比文件基础上常规加减即可获得的范畴，现有技术并未给出构建该组方的技术启示，本申请权利要求 1-2 符合专利法第二十二条第三款所规定的创造性。被诉决定对此认定有误，北京知识产权法院判决撤销被诉复审决定，并判令国家知识产权局重新作出审查决定。判决作出后，双方当事人均未提起上诉，本案一审判决已生效。

2.典型意义

本案明确了中药组方发明专利创造性判断的具体规则，

对为中医药传承创新与知识产权司法保护具有指引价值。法院没有局限于药材组分的逐一比对，而是深入中医方剂学的专业语境，充分理解“君臣佐使”的配伍逻辑与“标本兼治”的辨证施治理念，明确中药组合物发明的核心价值在于整体配伍关系和组方结构，而非简单的药材堆砌。中医药主体撰写申请专利文件，应清楚记载发明对应的疾病病机分析、治法治则、完整方解以及配伍逻辑，说明组方药味取舍、炮制规格变更、重量配比选择的理由，真正体现出中药组方与现有技术相比病机、治则、组方主次结构上的创新贡献。

案例三：“甲苯磺酸艾多沙班片”药品专利链接纠纷案
——仿制药技术方案变更后的认定问题

1.基本案情

涉案专利系名称为“药物组合物”的发明专利，专利权人为某株式会社。涉案专利被登记在中国上市药品专利信息登记平台上，并与某株式会社批准上市的甲苯磺酸艾多沙班片（简称涉案原研药）相关联，涉案原研药的适应症为成人深静脉血栓和肺栓塞等。海某公司以涉案原研药为参比制剂向国家药品监督管理局提交的甲苯磺酸艾多沙班片仿制药（简称涉案仿制药）的上市许可申请已被受理。针对涉案专利，海某公司提交了4.1类声明，即被仿制药相关专利权应当被宣告无效。根据国家药品监督管理局药品审评中心发出的《补充资料通知》，海某公司变更了涉案仿制药薄膜包衣预混剂的成分，国家药监局药审中心依据变更后的涉案仿制药申报方案完成了技术审评。此外，就某株式会社依据涉案专利提出的药品专利纠纷行政裁决申请，国家知识产权局作出行政裁决，确认涉案仿制药相关技术方案落入涉案专利权利要求2和11的保护范围。

海某公司诉至北京知识产权法院，请求确认涉案仿制药变更后的技术方案未落入涉案专利权利要求2和11的保护范围。北京知识产权法院经审理认为，涉案仿制药的技术方案以变更后的内容为准，因变更后的技术方案与涉案专利权利要求2、11既不相同亦不等同，故判决确认涉案仿制药未

落入涉案专利权利要求 2、11 的保护范围。判决作出后，某株式会社向最高人民法院提起上诉，二审维持原判。

2.典型意义

本案明确了对变更后的仿制药技术方案确定的标准。本案通过详细剖析仿制药申请人在技术审评过程中变更技术方案的具体情况，明确了变更后的技术方案在得到药品审评机构接受后，即成为判断是否落入专利权保护范围的依据。本案不仅为仿制药企业在技术变更后有效维护自身权益提供了明确的法律指引，而且还保障了专利权人与仿制药企业之间的利益平衡。

案例四：“盐酸鲁拉西酮片”药品专利链接纠纷案
——专利状态不稳定时参照适用“先行裁驳，另行起诉”

1.基本案情

涉案专利系名称为“药物组合物”的发明专利，专利权人为住某株式会社。涉案专利被登记在中国上市药品专利信息登记平台（简称登记平台）上，并与住某株式会社批准上市的盐酸鲁拉西酮片（简称涉案原研药）相关联，涉案原研药的适应症为精神分裂症等。华某公司以涉案原研药为被仿制药向国家药品监督管理局提交的盐酸鲁拉西酮片仿制药（简称涉案仿制药）的上市许可申请已被受理。针对涉案专利，华某公司提交了2类声明，即登记平台收录的被仿制药相关专利权已终止或者被宣告无效。针对涉案专利，国家知识产权局作出决定，宣告其全部无效，该决定处于行政诉讼阶段。住某株式会社诉至北京知识产权法院，请求确认涉案仿制药落入涉案专利权的保护范围。北京知识产权法院经审理认为，涉案专利权已被国家知识产权局宣告无效，裁定驳回住某株式会社的起诉。裁定作出后，住某株式会社向最高人民法院提起上诉，二审维持原裁定。

2.典型意义

本案是最早采用驳回起诉做法处理专利权状态不稳定的药链案件。本案从药链制度的设立目的出发，结合制度定位，立足平衡双方当事人的利益，分析在药链案件中参照适用专利侵权案件“先行裁驳，另行起诉”规定的合理性和必

要性，对于类似案件的审理具有借鉴意义，有效避免了司法资源的浪费。

案例五：“艾地骨化醇胶囊”药品专利链接纠纷案
——专利状态不稳定时仿制药企申请实体审理的处理

1.基本案情

涉案专利系名称为“ED-71 制剂”的发明专利，专利权人为中某株式会社。涉案专利被登记在中国上市药品专利信息登记平台（简称登记平台）上，上述权利要求与中某株式会社批准上市的艾地骨化醇胶囊(简称涉案原研药)相关联，涉案原研药的适应症为骨质疏松症等。海某公司以涉案原研药为被仿制药向国家药品监督管理局提交的艾地骨化醇胶囊化学药品 4 类仿制药（简称涉案仿制药）的上市许可申请已被受理。针对涉案专利，海某公司提交了 4.2 类声明，即涉案仿制药未落入登记平台收录的被仿制药品相关专利权保护范围。中某株式会社诉至北京知识产权法院，请求确认涉案仿制药落入涉案专利权利要求的保护范围。北京知识产权法院经审理认为，考虑海某公司明确申请进行实体审理，结合本案其他相关因素，认定涉案仿制药并未落入涉案专利的保护范围，判决驳回中某株式会社的诉讼请求。判决作出后，中某株式会社向最高人民法院提起上诉，二审维持原判。

2.典型意义

本案系药链专利链接制度施行以来法院受理并审结的首案。该案对专利权利状态不稳定时的审理规则进行了细化，即仿制药企明确向法院申请对案件进行实体审理的，可以进行实体审理。本案彰显了司法机关在保障药品可及性与鼓励

医药创新之间的平衡考量，为后续类似案件的处理提供了重要参考与指引。

案例六：“哌柏西利片”药品专利链接纠纷案
——四类声明的认定标准及
原研药在我国境内未上市时一类声明的判断标准

1.基本案情

涉案专利系名称为“2-(吡啶-2-基氨基)-吡啶并[2,3-d]嘧啶-7-酮”的发明专利，专利权人为朗某公司。涉案专利被登记在中国上市药品专利信息登记平台（简称登记平台）上，并与某丙公司批准上市的哌柏西利胶囊相关联。涉案药品的适应症为乳腺癌等。齐某公司以某丙公司未在我国批准上市的哌柏西利片（简称涉案原研药）为被仿制药向国家药品监督管理局提交的哌柏西利片化学3类仿制药（简称涉案仿制药）的上市许可申请已被受理。针对涉案专利，齐某公司提交了1类声明，即登记平台中没有被仿制药的相关专利信息。朗某公司诉至北京知识产权法院，请求确认涉案仿制药落入涉案专利权利要求1-4的保护范围。北京知识产权法院经审理认为，涉案专利作为哌柏西利“胶囊”相关专利的登记，不能视为哌柏西利“片”相关专利的登记，涉案仿制药属于一类声明的情形，朗某公司的起诉不符合受理条件，裁定驳回朗某公司的起诉。裁定作出后，朗某公司向最高人民法院提起上诉，二审维持原裁定。

2.典型意义

本案涉及四类声明的认定问题。四类声明是《最高人民法院关于审理申请注册的药品相关的专利权纠纷民事案件

适用法律若干问题的规定》第三条规定的受理条件之一，本案从药链制度价值出发，分析了采用应然标准判断是否属于四类声明的原因，明确了采用排除法进行实质判断的步骤，为类似案件的审理提供了重要指导和参考，在保障当事人合法权益的同时，节约了司法资源。

此外，本案还明确了在涉案原研药未在我国境内上市的情况下，对于药品专利纠纷早期解决机制中一类声明的判断标准。即不能简单地将已在我国登记平台中作为其他上市药品相关专利的信息，直接视为该未上市原研药的相关专利登记信息，即便二者仅剂型不同。这一裁判规则有助于准确界定药品专利纠纷早期解决机制的保护范围，避免因原研药未上市而产生的错误声明问题，保障了仿制药企业的合法权益，同时也促进了药链机制的合理运用和有效实施。

案例七：〝富马酸伏诺拉生片〞药品专利链接纠纷案
——仿制药申请人的举证责任

1.基本案情

涉案专利系名称为“药物组合物”的发明专利，专利权人为武某株式会社。涉案专利的权利要求 1-4 被登记在中国上市药品专利信息登记平台（简称登记平台）上，上述权利要求与武某株式会社批准上市的富马酸伏诺拉生片（简称涉案原研药）相关联，涉案原研药的适应症为胃酸相关性疾病（ARDs）等。英某公司以涉案原研药为被仿制药向国家药品监督管理局提交的富马酸伏诺拉生片化学 4 类仿制药（简称涉案仿制药）的上市许可申请已被受理。英某公司在提交上市许可申请时未针对涉案专利作出专利声明。武某株式会社诉至北京知识产权法院，请求确认涉案仿制药落入涉案专利权利要求 1-2 的保护范围。北京知识产权法院经审理认为，英某公司经合法传唤未出庭，且在一审答辩期及法院另行指定的举证期限内均未提交涉案仿制药必要技术资料等任何证据，属于控制证据无正当理由拒不提交的情形，故判决涉案仿制药的技术方案落入涉案专利权利要求 1-2 的保护范围。判决作出后，各方当事人均未提起上诉，本案一审判决已生效。

2.典型意义

本案涉及举证责任的分配问题，主要解决的是当事人不举证的情况下，如何确定涉案仿制药技术方案的问题，并进

一步明确了仿制药申请人不提交申报资料的法律后果。本案通过合理分配举证责任，保护了专利权人的合法权益，有效维护了药品市场的公平竞争秩序。

案例八：“乌帕替尼缓释片”其他专利行政纠纷案
——马库什化合物保护范围的界定

1.基本案情

被诉裁决系国家知识产权局就A某公司针对某某公司提出的药品专利纠纷行政裁决请求而作出，被诉裁决涉及发明名称为“新的三环化合物”的发明专利。被诉裁决认定，确认“乌帕替尼缓释片”仿制药技术方案落入涉案专利权利要求1-3的保护范围。原告某某公司不服被诉裁决，认为由于乌帕替尼这一具体化合物已被宣告无效，应当被视为“坏点”，被排除在权利要求1-3的保护范围外。且乌帕替尼半水合物与乌帕替尼系不同物质，不属于相同技术特征。北京知识产权法院经审理认为，乌帕替尼化合物作为落入权利要求1的技术方案，其作为权利要求4的技术方案被宣告无效，这一情形仅意味着乌帕替尼化合物不能获得相较于落入权利要求1保护范围内的其他化合物不同的保护，但其仍可获得与权利要求1保护范围之内其他化合物相同的保护。且仿制药技术方案中乌帕替尼半水合物包含乌帕替尼全部技术特征，故落入权利要求1-3保护范围，被诉决定认定并无不当。据此法院判决驳回原告的诉讼请求。一审判决作出后，某某公司不服提起上诉，最高人民法院于2026年4月30日作出二审判决，驳回上诉，维持原判。

2.典型意义

本案针对实践中出现的马库什化合物权利要求被维持

有效，而落入该权利要求的具体化合物权利要求被无效的特殊情况下，如何界定马库什化合物权利要求的保护范围作出认定。本案通过厘清马库什化合物权利要求和具体化合物权利要求之间的关系，明确了具体化合物权利要求被无效并不影响落入通式化合物保护范围的具体化合物技术方案仍然有效，具体化合物被宣告无效仅意味着其不能获得相较于通式化合物保护范围内其他化合物不同的保护。同时，本案还明确了对于化合物技术方案的比对标准，即不以物质进行整体比对，仍应基于技术特征进行比对。该案为涉及马库什化合物的技术方案比对提供了明确的规则指引。

案例九：〝乌帕替尼缓释片〞是否符合受理条件药品专利链接纠纷案

——不当声明时声明这一受理条件的认定标准

1.基本案情

涉案专利是名称为“新的三环化合物”的发明专利，专利权人为A某公司。涉案专利的权利要求1-3、6-8和15与乌帕替尼缓释片相关联。上述信息已被登记在中国上市药品专利信息登记平台上，且已被公开。北某公司以前述乌帕替尼缓释片为被仿制药，向国家药品监督管理局提交的乌帕替尼缓释片化学4类仿制药的上市许可申请已被受理，北某公司针对涉案专利均提交了2类声明。A某公司诉至北京知识产权法院，请求确认前述仿制药落入涉案专利权利要求1-3的保护范围。北京知识产权法院经审理认为，北某公司作出“二类”声明时，涉案权利要求已被国家知识产权局决定维持，故仿制药企作出前述不当声明，存在主观过错。在此基础上，即便仿制药企具有变更为“三类声明”的意思表示，亦无法认定其作出三类声明。据此，可推定仿制药企应作出四类声明，该案符合药链案件受理条件，法院最终经实体审理判决涉案仿制药的技术方案落入涉案专利权利要求1-3的保护范围。判决作出后，各方当事人均未提起上诉，该案一审判决已生效。

2.典型意义

在司法实践中，对于《最高人民法院关于审理申请注册

的药品相关的专利权纠纷民事案件适用法律若干问题的规定》第三条中“四类声明”的理解，已确立了声明认定采用“应然状态”的判断标准，即对登记平台所登记的声明作实质审查。而本案系对前述标准的进一步细化。针对仿制药企作出“二类”声明不当的情形，即便被告具有变更为“三类声明”的意思表示，但在综合考量仿制药企作出不当声明存在主观过错，双方无法就承诺事项达成一致的情况下，无法认定案涉情形属于“三类声明”的情形。在此基础上，可推定仿制药企作出四类声明，该案符合药品专利链接案件受理条件。该规则旨在规制仿制药企不诚信地利用不同声明之间的差异获得不当利益的行为，引导仿制药企如实作出声明，从而保证药链制度价值充分发挥与有效运行。

Beijing Intellectual Property Court's Typical Cases concerning Pharmaceutical Patent

Case 1: Administrative Dispute over Invalidation of the "Baloxavir Prodrug" Invention Patent

—Determining whether a Markush compound claim is supported by the specification

1.Basic facts

The patent, entitled "Prodrugs of Substituted Polycyclic Carbamoylpyridone Derivatives," is owned by a pharmaceutical company referred to here as Shio*. It contains nine claims. Independent claim 1 concerns a compound defined by a general formula, or a pharmaceutically acceptable salt thereof.

An individual, Liu*, requested that the China National Intellectual Property Administration ("CNIPA") invalidate the patent. CNIPA decided to maintain its validity. Liu* brought an administrative action before the Beijing Intellectual Property Court, arguing that the drug activity and preparation methods of the "tricyclic" compounds covered by claim 1 were not supported by the specification. Liu* contended that claim 1 covered numerous tricyclic compounds with substantially different core structures, whereas the specification disclosed

only six examples of their preparation and one example of their effects. The claim's generalization therefore exceeded the disclosure.

The court held that the specification supported both the drug activity and the methods of preparing the tricyclic compounds in claim 1. The claim complied with Article 26(4) of the 2009 *Patent Law of the People's Republic of China*. The court dismissed Liu*'s claims. No party appealed, and the first-instance judgment took effect.

2. Significance

Whether a Markush compound claim is supported by the specification is a difficult question in pharmaceutical patent grant and validity proceedings. Both Markush claim drafting and the support requirement involve generalization, but the applicable standard needs clarification.

The invention sought to convert compounds from an earlier invention into prodrugs. Its parent compound, baloxavir, was described in the case materials as a novel anti-influenza drug pioneered by the patent owner and, at the time, the first and only single-dose oral influenza treatment approved by the National Medical Products Administration, marketed under the trade name Xofluza. The judgment defines the nature of a Markush claim and clarifies the support standard applicable to it. It provides drafting guidance, improves predictability concerning

patent validity, and helps pharmaceutical companies build effective patent protection systems.

Case 2: Administrative Dispute over Reexamination of the Rejected "Kuanxiong Liqi Oral Liquid" Patent Application

—Rules for assessing the inventiveness of a TCM formulation invention

1. Basic facts

The applicant for the invention patent application entitled "Kuanxiong Liqi Oral Liquid" was a TCM research institute. CNIPA upheld the rejection of the application on reexamination. The institute brought an administrative action, arguing that the decision had overlooked the application's distinctive understanding of disease mechanism, treatment principles, and "jun-chen-zuo-shi" formulation structure—the traditional roles of chief, deputy, assistant, and envoy ingredients. It argued that the formulation could not be deemed obvious solely on the basis of the effects of individual medicinal ingredients.

The Beijing Intellectual Property Court held that the inventiveness of a TCM composition cannot be assessed by simply adding together the known effects of its individual ingredients. From the perspective of a person skilled in the art, the formulation must be considered as a whole, including its understanding of disease mechanism, treatment principles, ingredient compatibility and hierarchy, selection of ingredients, and dosage ratios.

Although the application and the cited prior-art document shared some ingredients, their underlying understanding of disease mechanism and treatment approach differed. The compatibility structure had been reconfigured beyond the routine addition or omission of ingredients that a skilled person might derive from the prior art. The prior art gave no technical motivation to construct the claimed formulation. Claims 1 and 2 therefore met the inventiveness requirement in Article 22(3) of the Patent Law. The court revoked the reexamination decision and ordered CNIPA to make a new decision. Neither party appealed, and the judgment took effect.

2. Significance

This case clarifies how to assess the inventiveness of TCM formulation patents. Rather than comparing ingredients one by one, the court examined the professional framework of TCM prescription theory, including the logic of “jun-chen-zuo-shi” compatibility and treatment based on the patient’s condition and the underlying cause. It recognized that the core contribution of a TCM composition may lie in its overall compatibility relationships and structure, not merely in the collection of ingredients.

TCM applicants should clearly document disease-mechanism analysis, treatment principles, a complete explanation of the formulation, and ingredient-compatibility

logic. They should explain decisions concerning ingredient selection, processing specifications, and weight ratios, so that the application demonstrates its innovative contribution over the prior art.

Case 3: "Edoxaban Tosylate Tablets" Pharmaceutical Patent Linkage Dispute

—Identifying a generic drug's technical solution after amendment

1. Basic facts

The patent, entitled "Pharmaceutical Composition," was owned by a company referred to here as Company K. It was listed on the Patent Information Registration Platform for Drugs Marketed in China in connection with Company K's approved edoxaban tosylate tablets, an original drug indicated for conditions including deep vein thrombosis and pulmonary embolism in adults.

A company referred to here as Hai* used the original drug as its reference product and submitted an application to the National Medical Products Administration for marketing authorization for generic edoxaban tosylate tablets. The application was accepted. Hai* submitted a Category 4.1 declaration asserting that the relevant patent should be invalidated. Following a request for supplementary materials from the Center for Drug Evaluation, Hai* changed the composition of the generic drug's film-coating premix. The Center completed its technical review on the basis of the amended application.

Separately, in response to Company K's request for an administrative adjudication concerning the patent, CNIPA confirmed that the generic drug's relevant technical solution fell within the scope of claims 2 and 11. Hai* then brought an action before the Beijing Intellectual Property Court seeking confirmation that its amended solution did not fall within those claims.

The court held that the amended solution governed. Because it was neither identical nor equivalent to the solutions protected by claims 2 and 11, the court confirmed that the generic drug did not fall within their scope. Company K appealed to the Supreme People's Court, which upheld the judgment.

2. Significance

The case establishes a standard for identifying a generic drug's technical solution after amendment. Once an amended solution has been accepted by the drug review authority, it becomes the basis for determining whether the drug falls within the patent's scope of protection. This provides guidance to generic companies making changes during review while maintaining a balance between their interests and those of patent owners.

Case 4: "Lurasidone Hydrochloride Tablets" Pharmaceutical Patent Linkage Dispute

—Applying by reference the approach of "dismissing the action first, while permitting a separate action later" when patent status is unstable

1. Basic facts

The patent, entitled "Pharmaceutical Composition," was owned by a company referred to here as Sumi*. It was listed on the Patent Information Registration Platform for Drugs Marketed in China in connection with the company's approved lurasidone hydrochloride tablets, indicated for conditions including schizophrenia.

A company referred to here as Hua* submitted an application for marketing authorization for generic lurasidone hydrochloride tablets, using the originator drug as its reference product. The application was accepted. Hua* filed a Category II declaration stating that the patent listed for the reference drug had expired or been invalidated. CNIPA had declared the patent invalid in its entirety, although that decision was under administrative judicial review.

Sumi* brought an action seeking confirmation that the generic drug fell within the patent's scope of protection. The Beijing Intellectual Property Court dismissed the action because

CNIPA had declared the patent invalid. The Supreme People's Court upheld that ruling on appeal.

2. Significance

This was one of the earliest patent linkage cases in which an action was dismissed because the patent's status was unstable. Taking account of the linkage system's purpose and the interests of both parties, the court explained why it was appropriate to apply by reference the approach used in patent infringement litigation of dismissing the current action while allowing a separate action later. The ruling provides a reference for similar cases and avoids unnecessary expenditure of judicial resources.

Case 5: "Eldecalcitol Capsules" Pharmaceutical Patent Linkage Dispute

—Proceeding to substantive adjudication at a generic company's request when patent status is unstable

1. Basic facts

The patent, entitled "ED-71 Formulation," was owned by a company referred to here as Chu*. It was listed on the Patent Information Registration Platform for Drugs Marketed in China in connection with the company's approved eldecalcitol capsules, indicated for conditions including osteoporosis.

A company referred to here as Hai* submitted an accepted marketing authorization application for a Class 4 chemical generic of the capsules, using the original drug as its reference product. Hai* filed a Category 4.2 declaration asserting that its generic drug did not fall within the protection scope of the listed patent.

Chu* brought an action seeking confirmation that the generic drug fell within the patent's scope. Taking account of Hai*'s express request for adjudication on the merits and other relevant circumstances, the Beijing Intellectual Property Court examined the substance of the dispute. It found that the generic drug did not fall within the patent's scope and dismissed the patent owner's claims. The Supreme People's Court upheld the

judgment on appeal.

2. Significance

This was the first case accepted and concluded by a court following the implementation of the pharmaceutical patent linkage system. It refines the rules for cases involving unstable patent status: where the generic company expressly requests substantive adjudication, the court may hear the merits. The decision reflects the need to balance drug accessibility with incentives for pharmaceutical innovation.

Case 6: "Palbociclib Tablets" Pharmaceutical Patent Linkage Dispute

—Standards for assessing Category IV declarations and Category I declarations where the originator drug has not been marketed in China

1. Basic facts

The patent, entitled "2-(Pyridin-2-ylamino) -pyrido[2,3-d] pyrimidin-7-one," was owned by a company referred to here as Lang*. It was listed on the Patent Information Registration Platform for Drugs Marketed in China in connection with palbociclib capsules approved for marketing by Company C. The drug was indicated for conditions including breast cancer.

A company referred to here as Qi* submitted an accepted application for a Class 3 chemical generic of palbociclib tablets. Its reference product was palbociclib tablets that had "not" been approved for marketing in China. Qi* filed a Category I declaration stating that the platform contained no relevant patent information for the drug it sought to copy.

Lang* brought an action seeking confirmation that the generic tablets fell within the scope of patent claims 1–4. The Beijing Intellectual Property Court held that registration of the patent in connection with palbociclib "capsules" could not be treated as registration in connection with palbociclib "tablets".

The generic application fell within the circumstances of a Category I declaration, and the action did not meet the conditions for acceptance. The court dismissed it. The Supreme People's Court upheld the ruling.

2. Significance

The case addresses how to assess the four categories of patent declarations. A Category IV declaration is one of the conditions for accepting a linkage case under Article 3 of the Supreme People's Court's relevant judicial provisions. Considering the purpose of the linkage system, the court explained why declarations should be assessed according to the category that "ought" to have been made, rather than solely by the label supplied by the applicant, and clarified a process of elimination for making that substantive assessment.

The case also clarifies the Category I standard where the original drug has not been marketed in China. Patent information listed for another marketed drug cannot automatically be treated as patent information registered for the unmarketed reference drug, even if the products differ only in dosage form. This helps define the scope of the early resolution mechanism, protects generic applicants' legitimate interests, and promotes proper use of the system.

Case 7: "Vonoprazan Fumarate Tablets" Pharmaceutical Patent Linkage Dispute

—The generic applicant's burden of proof

1. Basic facts

The patent, entitled "Pharmaceutical Composition," was owned by a company referred to here as Taked*. Claims 1–4 were listed on the Patent Information Registration Platform for Drugs Marketed in China in connection with the company's approved vonoprazan fumarate tablets, indicated for acid-related disorders and other conditions.

A company referred to here as Ying* submitted an accepted application for a Class 4 chemical generic of the tablets, using the originator drug as its reference product. It did not make a patent declaration concerning the patent when submitting its marketing authorization application.

Taked* brought an action seeking confirmation that the generic drug fell within the scope of claims 1 and 2. Despite being duly summoned, Ying* did not appear in court. It also failed to submit the necessary technical materials or any other evidence concerning its generic drug within either the original response period or the additional period set by the court. The Beijing Intellectual Property Court found that Ying* controlled the evidence but had refused to produce it without justification.

It therefore held that the generic drug's technical solution fell within the scope of claims 1 and 2. No party appealed, and the judgment took effect.

2. Significance

This case concerns how to determine a generic drug's technical solution when the applicant fails to produce evidence. It clarifies both the allocation of the burden of proof and the consequences of withholding application materials. By assigning that burden appropriately, the judgment protects the patent owner's legitimate interests and supports fair competition in the drug market.

Case 8: "Upadacitinib Extended-Release Tablets" Patent-Related Administrative Dispute

—Defining the scope of protection of a Markush compound claim

1. Basic facts

The challenged administrative adjudication was issued by CNIPA in response to a pharmaceutical patent dispute request made by Company A against another company. It concerned an invention patent entitled "Novel Tricyclic Compounds." CNIPA found that the technical solution for generic upadacitinib extended-release tablets fell within the scope of claims 1–3.

The generic company brought an administrative action. It argued that, because the claim specifically directed to upadacitinib had been invalidated, the compound should be treated as a "bad point" excluded from the scope of claims 1–3. It also argued that upadacitinib hemihydrate and upadacitinib were different substances and did not constitute the same technical feature.

The Beijing Intellectual Property Court held that upadacitinib remained a technical solution falling within claim 1. The invalidation of claim 4, which specifically claimed that compound, meant only that upadacitinib could not receive protection different from that afforded to other compounds

within claim 1. It could still receive the same protection under claim 1 as those other compounds. The court further held that the upadacitinib hemihydrate in the generic technical solution contained all the technical features of upadacitinib and therefore fell within claims 1–3. It dismissed the plaintiff's claims. On April 30, 2026, the Supreme People's Court dismissed the appeal and upheld the first-instance judgment.

2. Significance

The case addresses how to define the scope of a valid Markush compound claim when a claim to a specific compound within it has been invalidated. Invalidation of the specific-compound claim does not remove that compound's technical solution from the scope of the valid general-formula claim. It means only that the compound cannot receive a distinct level of protection relative to other compounds covered by the general claim.

The case also clarifies that compound-related technical solutions should be compared by their technical features, rather than by comparing substances as indivisible wholes. It provides guidance for future disputes involving Markush compounds.

Case 9: "Upadacitinib Extended-Release Tablets" Pharmaceutical Patent Linkage Dispute Concerning Whether Acceptance Requirements

—Determination Standard for the Acceptance Condition of Declaration in Cases of Improper Declaration

1. Basic facts

The patent, titled "Novel Tricyclic Compounds," is owned by Company A. Claims 1–3, 6–8 and 15 were associated with upadacitinib extended-release tablets, and that information had been published on the China Marketed Drug Patent Information Registration Platform.

Bei Company's application for marketing authorization for a Class 4 chemical generic version of those tablets was accepted. It submitted Type II declarations concerning the patent. Company A sued in the Beijing Intellectual Property Court, seeking confirmation that the generic drug fell within Claims 1–3.

The Beijing Intellectual Property Court, after trial, held that when Bei Company made its Type II declarations, the claims at issue had already been decided by the CNIPA to be maintained. Therefore, the generic drug company was subjectively at fault in making the aforementioned improper declarations. Where the parties were unable to reach agreement on the commitments, it

cannot be found that it made Type III declarations. The Court inferred that the generic-drug company ought to have made Type IV declarations and held that the action met the acceptance requirements. After examining the merits, it ruled that the generic-drug technical solution fell within Claims 1–3. No party appealed, and the first-instance judgment took effect.

2. Significance

Judicial practice has established a substantive, or "ought-to-have-been" standard for determining whether a declaration qualifies as Category IV under Article 3 of the Supreme People's Court's relevant judicial provisions. This means examining the substance of the declaration recorded on the platform. The present case further refines that standard.

In circumstances where a generic drug company improperly made a Type II declaration, even if the defendant expressed an intention to change it to a Type III declaration, where—after comprehensively considering that the generic drug company was subjectively at fault in making the improper declaration and that the parties were unable to reach agreement on the commitments—it cannot be found that the circumstances of the case fall within those of a Type III declaration. On this basis, it may be presumed that the generic drug company made a Type IV declaration, and the case meets the acceptance requirements for a drug patent linkage case. This rule is

intended to regulate the conduct of generic drug companies in dishonestly exploiting differences among declarations to obtain improper benefits, guide generic drug companies to make declarations truthfully, and thereby ensure the full realization and effective operation of the value of the drug patent linkage system.