经营者集中审查行政诉讼第一案

一案三书（中英文版）

国家市场监督管理总局法　规　司
国家市场监督管理总局反垄断二司　指导
国家市场监督管理总局竞争政策与评估中心　编译

前　言

2024年12月30日，北京知识产权法院对北京托毕西药业有限公司（以下简称托毕西）诉市场监管总局案依法作出判决，驳回原告托毕西的诉讼请求。托毕西在法定期限内未提起上诉，该判决已正式生效。该案是2008年《中华人民共和国反垄断法》施行以来第一例经营者集中审查行政诉讼案，具有重要示范效应。

本次判决涉及市场监管总局于2023年9月依法对先声药业有限公司（以下简称先声药业）收购托毕西股权交易作出的2023年第42号决定（以下简称被诉决定）。市场监管总局对交易全面审查后，认定交易对中国境内巴曲酶注射液市场可能具有排除、限制竞争效果，要求先声药业和集中后实体履行解除独家协议、剥离在研业务、下调药品价格等义务。托毕西不服被诉决定，于法定期限内向市场监管总局申请行政复议。2024年2月，市场监管总局作出国市监复议〔2023〕127号行政复议决定，维持被诉决定。托毕西于2024年3月提起行政诉讼。北京知识产权法院组织诉讼各方进行了证据交换和质证，认定市场监管总局作出的决定认定事实清楚、适用法律正确、程序合法，判决驳回托毕西的诉讼请求。

为便于相关经营主体、反垄断实务工作者、专家学者等全面了解案情，我们组织编译了本案“一案三书”（即审查决定、行政复议决定书、判决书）的中英文版，供大家在学习工作中参考。

目　　录

一、审查决定

市场监管总局关于附加限制性条件批准先声药业有限公司收购北京托毕西药业有限公司股权案反垄断审查决定的公告

市场监管总局依据《中华人民共和国反垄断法》（以下简称《反垄断法》）对先声药业有限公司（以下简称先声药业）收购北京托毕西药业有限公司（以下简称托毕西）股权案（以下称本案）进行了经营者集中反垄断审查，决定附加限制性条件批准此项经营者集中。根据《反垄断法》第三十六条规定，现公告如下：

一、立案和审查程序

2022 年 6 月 29 日、7 月 20 日，托毕西、先声药业分别自愿向市场监管总局提交本案经营者集中申报材料。经审核，市场监管总局认为该申报材料不完备，要求申报方予以补充。11 月 23 日，市场监管总局确认经补充的申报材料符合《反垄断法》第二十八条规定，本案未达到申报标准，但是经审查认为有必要立案，按照《反垄断法》和《经营者集中审查暂行规定》第十二条、十三条、十六条规定，对此项经营者集中予以立案并开始初步审查。12 月 21 日，市场监管总局决定对此项经营者集中实施进一步审查。2023 年 3 月 19 日，经申报方同意，市场监管总局决定延长进一步审查期限。4 月 25 日，市场监管总局根据《反垄断法》《经营者集中审查规定》对本案作出中止计算审查期限的决定；并于

9 月 21 日继续计算审查时限。目前，本案处于进一步审查延长阶段，截止日为 2023 年 10 月 13 日。市场监管总局认为，此项集中对中国境内巴曲酶注射液市场可能具有排除、限制竞争效果。

在审查过程中，市场监管总局征求有关政府部门、行业协会和相关企业意见，调研医院、专业机构等相关单位，同法律、经济专家深入座谈，了解相关市场界定、市场结构、行业特征和集中对各方面影响等信息，聘请独立第三方机构对本案竞争问题进行经济分析，并对申报方提交的文件、材料真实性、完整性和准确性进行了审核。

二、案件基本情况

（一）参与集中的经营者基本情况。

收购方：先声药业。1998 年在江苏省南京市设立，母公司先声药业集团有限公司在中国香港设立，于香港联合交易所上市，最终控制人为自然人。先声药业及关联方（以下统称为先声药业）主要从事药品生产和销售。

被收购方：托毕西。1993 年在北京市设立。托毕西股权持有人为子博有限公司，在中国香港设立，最终控制人为自然人。托毕西从事巴曲酶注射液生产和销售。

（二）交易过程。

2017 年 7 月，先声药业与子博有限公司签订协议，拟收购托毕西全部股权。集中至今未实施。

2019 年 4 月，先声药业与全球巴曲酶浓缩液原料药（以下简

称巴曲酶原料药）唯一供应商瑞士 DSM Nutritional Products Ltd Branch Pentapharm（以下将该公司与其关联方统称为 DSM）签订《合作及供货协议》，成为中国境内市场唯一可以销售巴曲酶原料药的公司。

三、相关市场

经查，先声药业从事巴曲酶原料药销售，托毕西从事巴曲酶注射液生产与销售，二者存在纵向关系。同时，先声药业正在从事巴曲酶注射液研发，与托毕西存在横向重叠。

（一）相关商品市场。

1.巴曲酶原料药销售。

巴曲酶是世界卫生组织对巴西矛头蛇（Bothrops atrox）蛇毒中所含的纤维蛋白促凝蛋白酶的通用名。巴西矛头蛇有 5 个亚种，其中一个亚种 Bothrops moojeni 蛇毒所含的巴曲酶具有去纤维蛋白原作用，可用于溶栓，又称为去纤酶，而来自其他亚种的巴曲酶具有促凝血特性，可用于止血，又称为凝血酶。二者在理化性质、生化特点、作用等方面不同，属于不同的相关市场。巴曲酶原料药属于去纤酶。

巴曲酶原料药主要用于生产巴曲酶注射液。从需求替代分析，根据《中华人民共和国药品管理法》第二十八条规定，药品应当符合国务院药品监督管理部门颁布的《中华人民共和国药典》和药品标准。根据《中华人民共和国药典》和巴曲酶注射液的药品注册批文，巴曲酶原料药是生产巴曲酶注射液的唯一原料药，其

成分不能被其他任何原料药替代。巴曲酶原料药与其他原料药之间没有需求替代性。从供给替代分析，巴曲酶原料药在提取工艺、制作流程等方面有别于其他原料药，提取技术与仿制难度较高，所需的巴西矛头蛇需经严格鉴定并筛选，在特定环境下人工传代饲养，再从第 5—7 代巴西矛头蛇的毒液中提取蛇毒用于生产巴曲酶原料药。同时，原料药进入市场需要经过一系列临床测试，其他原料药企业短期内难以转产提供巴曲酶原料药。巴曲酶原料药与其他原料药之间没有供给替代性。

本案涉及巴曲酶原料药的销售，因此本案相关商品市场界定为巴曲酶原料药销售市场。

2.巴曲酶注射液。

巴曲酶注射液是中国境内巴曲酶原料药唯一下游应用，是一种降低纤维蛋白原药物，可降低血液中纤维蛋白原的含量，降低全血粘度和血浆粘度，使血管阻力下降，增加血流量。

该药品为日本东菱药品工业株式会社原研药，托毕西在中国境内进行生产和供应。该药品主要在日本、中国注册上市。在日本，注册批准的适应症为恢复突发性聋的听力并改善自觉症状，改善振动病的末梢循环障碍，改善慢性动脉闭塞症伴随的缺血性症状。在中国境内，注册批准的适应症为改善突发性聋、振动病等末梢及微循环障碍，改善各种闭塞性血管病引起的缺血性症状以及急性脑梗死。经调查，临床常见、规范使用巴曲酶注射液的场景主要为全频听力下降突发性聋的治疗。巴曲酶注射液在全频

听力下降突发性聋的治疗上，难以被其他药品替代，构成独立的相关商品市场。

根据中华医学会耳鼻咽喉头颈外科学分会《突发性聋诊断和治疗指南（2015）》，突发性聋指72小时内突然发生、原因不明的感音神经性听力损失，至少在相邻的两个频率听力下降≥20dBHL。按照听力损失累及的频率和程度，突发性聋分为高频下降性、低频下降性、平坦下降型和全聋型，其中平坦下降型和全聋型统称为全频听力下降。较公认的全频听力下降突发性聋可能的发病机制包括血管纹功能障碍或内耳血管痉挛、内耳血管栓塞或血栓形成。

对于全频听力下降突发性聋，根据治疗指南和临床实践，需要联合使用降低纤维蛋白原药物（如巴曲酶注射液）、糖皮质激素、改善内耳微循环药物（如银杏叶提取物等）。经调查，三类药物在治疗上各自发挥不同药理作用和功能，满足不同需求，降低纤维蛋白原药物无法被其他类别药物替代，其他类别药物生产商短期内也难以转产提供巴曲酶注射液，巴曲酶注射液构成独立的相关商品市场。

我国获批突发性聋适应症的降低纤维蛋白原药物仅有巴曲酶注射液和降纤酶注射液（或注射用降纤酶，以下统称为降纤酶注射液）。二者具有一定替代性，但是根据临床实际使用需求和产品供给情况，降纤酶注射液不构成巴曲酶注射液的较为紧密替代。

从需求替代分析，一是治疗指南和医保规范对临床用药选择有强力影响。《突发性聋诊断和治疗指南（2015）》列名用于治疗突发性聋的降低纤维蛋白原药物仅有巴曲酶注射液，未列名降纤酶注射液。使用巴曲酶注射液治疗突发性聋属于医保报销范围，使用降纤酶注射液治疗突发性聋不能医保报销。经调查，上述治疗指南和医保规范对临床用药有强力影响。二是巴曲酶注射液因用药经验、习惯、安全性等受到明显临床偏好。巴曲酶注射液 1993 年引入中国境内，使用经验丰富，疗效经过多年临床广泛验证，同时给药条件明确，便于避免不良反应。降纤酶注射液于 2003 年进入市场，治疗突发性聋的临床使用相对匮乏，给药条件也相对模糊。巴曲酶注射液较降纤酶注射液受到明显临床偏好。三是多家耳鼻喉科重点医院均表示，其使用巴曲酶注射液治疗全频听力下降突发性聋，未使用过降纤酶注射液。只有完全没有巴曲酶注射液供应，为尽最大可能救治患者，才会考虑使用降纤酶注射液。北京市巴曲酶注射液价格由 247 元/支提高至 358 元/支期间，被调研医院未转向使用降纤酶注射液治疗突发性聋。从供给替代分析，制剂进入市场需要经过一系列临床测试和监管审批，降纤酶注射液企业短期内难以转产提供巴曲酶注射液，巴曲酶注射液与降纤酶注射液之间没有供给替代性。综上，巴曲酶注射液不能被降纤酶注射液较为紧密替代，构成独立的相关商品市场。

（二）相关地域市场。

中国境内原料药和制剂均受到严格监管，必须获得有关部门

颁发的批文、药品生产许可证等资质，满足注册检验、专家评审、临床测试、定期检查等监管要求。国外生产的原料药和制剂在中国境内市场销售需获得药品进口批文，申请获得相关资质并满足监管要求需要较长时间。因此，巴曲酶原料药销售和巴曲酶注射液相关地域市场均界定为中国境内。

四、竞争分析

在全球范围内，巴曲酶原料药生产商仅有 DSM 一家。先声药业不掌握巴曲酶原料药的生产资料和技术，不具备生产巴曲酶原料药的能力，但是通过与 DSM 签订《合作及供货协议》，约定 DSM 在中国境内向其独家供应巴曲酶原料药，取得中国境内巴曲酶原料药的全部货源，控制中国境内巴曲酶原料药销售市场。该原料药在中国境内唯一下游应用为巴曲酶注射液，托毕西是目前中国境内巴曲酶注射液唯一生产商，先声药业正在研发巴曲酶注射液。

根据《反垄断法》第三十三条规定，市场监管总局从参与集中的经营者在相关市场的市场份额及其对市场的控制力、相关市场的市场集中度、集中对下游用户和其他有关经营者的影响等方面，深入分析了此项经营者集中对市场竞争的影响，认为此项集中对中国境内巴曲酶注射液市场可能具有排除、限制竞争效果。

（一）集中可能消除中国境内巴曲酶注射液市场潜在进入者，巩固托毕西在该市场的支配地位，产生排除、限制竞争效果。

托毕西在中国境内巴曲酶注射液市场份额为 100%，具有市

场支配地位。先声药业有巴曲酶注射液在研项目，已获批以日本东菱药品工业株式会社原研药为参比制剂进行仿制，2021 年 7 月获得药物临床试验批准，为中国境内巴曲酶注射液市场潜在进入者。经调查，仿制巴曲酶注射液最大难点之一在于制备或获取巴曲酶原料药。先声药业作为巴曲酶原料药中国境内唯一销售商，具有原料药获取的独特研发优势。目前中国境内从事巴曲酶注射液研发的经营者仅有先声药业一家。若先声药业仿制药临床试验成功并获批进入市场，将对托毕西现有产品带来竞争压力。集中直接消除了这一潜在竞争对手，巩固了托毕西在中国境内巴曲酶注射液市场的支配地位，可能产生排除、限制竞争效果。

（二）集中后实体可能实施原料封锁，对中国境内巴曲酶注射液市场产生排除、限制竞争效果。

1.集中后实体具有实施原料封锁，排除、限制中国境内巴曲酶注射液市场竞争的能力。

第一，集中后实体在中国境内巴曲酶原料药销售市场具有市场支配地位。通过与 DSM 签订《合作及供货协议》，先声药业取得中国境内巴曲酶原料药的全部货源，成为中国境内市场唯一可以销售巴曲酶原料药的公司，在中国境内巴曲酶原料药销售市场份额为 100%，具有市场支配地位，集中后实体将继受这一地位。

第二，集中后实体具有控制巴曲酶原料药销售市场的能力，下游经营者议价能力弱。先声药业取得中国境内巴曲酶原料药全部货源后，由于巴曲酶原料药是生产下游制剂巴曲酶注射液的唯

一原料药，下游制剂生产企业只能向其购买原料药，不存在转向其他供应商购买的可能，谈判能力弱，对先声药业以及集中后实体依赖程度高。

第三，其他经营者进入相关市场难度较大。其他经营者进入中国境内巴曲酶原料药销售市场需要有稳定的原料药供应。DSM 是全球巴曲酶原料药的唯一生产商，先声药业与 DSM 签订协议后，其他经营者难以从生产企业获得原料药供应。同时，巴曲酶原料药生产工艺复杂，仿制难度较大，其他企业短期内难以仿制或找到新的供货来源，进入相关市场难度大。

2.集中后实体具有实施原料封锁，排除、限制中国境内巴曲酶注射液市场竞争的动机。

仿制药上市后，往往以低于现有药品的价格销售，形成竞争约束，影响现有药品的销售数量和销售价格。目前中国境内巴曲酶注射液市场仅有托毕西一家供应商，集中后实体有动机通过封锁巴曲酶原料药供应或提高供应价格，阻碍其他竞争者进入市场，或获取更大利益。

3.集中可能对中国境内巴曲酶注射液市场具有排除、限制竞争效果。

集中后实体可能通过以下原料封锁方式排除、限制中国境内巴曲酶注射液市场竞争：一是集中后实体可能通过拒绝、限制或拖延向托毕西竞争对手提供巴曲酶原料药，阻碍其研发及生产；二是在托毕西与竞争对手之间实行差别待遇，向托毕西优先或排

他性提供相关产品、技术或服务等，阻碍竞争对手研发及生产；三是向托毕西竞争对手收取不合理高价等，提高竞争对手研发及生产成本。此项经营者集中完成后，将显著提高巴曲酶注射液市场进入门槛，打击其他企业研发、生产巴曲酶注射液的动力，巩固托毕西在下游中国境内巴曲酶注射液市场的支配地位。

五、附加限制性条件的商谈

审查过程中，市场监管总局将本案可能具有排除、限制竞争效果的审查意见及时告知申报方，并与申报方就如何减少此项经营者集中对竞争的不利影响等有关问题进行了多轮商谈。对先声药业提交的附加限制性条件承诺方案，市场监管总局按照《经营者集中审查规定》，重点从限制性条件的有效性、可行性和及时性方面进行了评估。

经评估，市场监管总局认为，先声药业于2023年8月25日提交的附加限制性条件承诺方案（见附件）可以减少此项经营者集中对竞争的不利影响，并降低患者用药成本。

六、审查决定

鉴于此项经营者集中在中国境内巴曲酶注射液市场可能具有排除、限制竞争效果，根据先声药业提交的附加限制性条件承诺方案，市场监管总局决定附加限制性条件批准此项集中，要求先声药业和集中后实体履行（包括但不限于）如下义务：

一是解除先声药业与DSM在中国境内独家、排他供应巴曲酶原料药的协议约定。

二是按照《经营者集中审查规定》规定的时限剥离先声药业在研巴曲酶注射液业务。向剥离买方承担巴曲酶原料药供应义务，并为剥离买方与 DSM 达成直接供应关系提供必要协助。

三是集中实施后下调临床常用规格的巴曲酶注射液终端价格不少于当前挂网价格的 20%。

四是集中实施后保障临床常用规格的巴曲酶注射液用药需求。

五是若未按时解除协议约定、未按时完成剥离或者剥离买方未按时实施研发，集中实施后下调临床常用规格的巴曲酶注射液终端价格不少于当前挂网价格的 50%。

限制性条件的监督执行除按本公告办理外，先声药业于 2023 年 8 月 25 日向市场监管总局提交的附加限制性条件承诺方案对先声药业和集中后实体具有法律约束力。

行为性条件自生效日起 6 年后，先声药业和集中后实体可以向市场监管总局提出解除条件的申请。市场监管总局将依申请并根据市场竞争状况作出是否解除的决定。未经市场监管总局批准解除，先声药业和集中后实体应继续履行限制性条件。

市场监管总局有权通过监督受托人或自行监督检查先声药业和集中后实体履行上述义务的情况。先声药业和集中后实体如未履行上述义务，市场监管总局将根据《反垄断法》相关规定作出处理。

本决定自公告之日起生效。

I. Review Decision

Announcement of the State Administration for Market Regulation Concerning the Anti-monopoly Review Decision to Approve Subject to Remedies the Acquisition of Equity in Beijing Tobishi Pharmaceutical Co., Ltd. by Simcere Pharmaceutical Co., Ltd.

The State Administration for Market Regulation (hereinafter referred to as "SAMR") conducted an anti-monopoly review of the concentration of undertakings regarding Simcere Pharmaceutical Co., Ltd. (hereinafter referred to as "Simcere")'s acquisition of equity in Beijing Tobishi Pharmaceutical Co., Ltd. (hereinafter referred to as "Tobishi") (hereinafter referred to as "the Case") pursuant to the Anti-Monopoly Law of the People's Republic of China (hereinafter referred to as "Anti-Monopoly Law"). SAMR decided to approve this concentration subject to remedies. In accordance with Article 36 of the Anti-Monopoly Law, the announcement is hereby issued as follows:

I. Case Filing and Review Procedures

On June 29 and July 20, 2022, Tobishi and Simcere voluntarily submitted notification materials for this concentration to SAMR respectively. After review, SAMR deemed the materials incomplete and requested supplements from the notifying parties. On November 23, SAMR confirmed that the supplemented materials complied with Article 28 of the Anti-Monopoly Law. Although the Case did not meet the notification threshold, SAMR determined it necessary to file. Pursuant to Articles 12, 13, and 16 of the Anti-Monopoly Law and the Interim Provisions on the Review of Concentration of Undertakings, SAMR formally filed the Case and initiated a preliminary review of this concentration. On December 21, SAMR decided to conduct a further review of this concentration. On March 19, 2023, with the consent of the notifying parties, SAMR extended the further review period. On April 25, SAMR decided to suspend the calculation of the review period for the Case pursuant to the Anti-Monopoly Law and the Provisions on the Review of Concentration of Undertakings; the review timeline resumed on September 21. Currently, the Case is in the extended phase of further review, with a deadline of October 13, 2023. SAMR considered that this concentration may likely have the effect of eliminating or restricting competition in China's batroxobin injection market.

During the review process, SAMR solicited opinions from relevant government departments, industry associations, and enterprises; conducted research with hospitals, professional institutions, and other related entities; held in-depth discussions with legal and economic experts to understand information on relevant market definition, market structure, industry characteristics, and the concentration's potential impacts; engaged an independent third-party institution to perform economic analysis on the competition issues of the Case; and reviewed the authenticity, completeness, and accuracy of documents and materials submitted by the notifying parties.

II. Basic Case Information

(i) Profiles of Undertakings Participating in the Concentration.

Acquiring Party: Simcere. Established in Nanjing, Jiangsu Province in 1998, its parent company, Simcere Pharmaceutical Group Limited, was incorporated in Hong Kong, China, and listed on the Hong Kong Stock Exchange, with its ultimate controller being a natural person. Simcere and its affiliates (collectively referred to as "Simcere") are primarily engaged in the production and sale of pharmaceuticals.

Acquired Party: Tobishi. Established in Beijing in 1993, Tobishi's equity holder is Zibo Co., Ltd., incorporated in Hong Kong, China, with its ultimate controller being a natural person. Tobishi is engaged in the production and sale of batroxobin injection.

(ii) Transaction Process.

In July 2017, Simcere entered into an agreement with Zibo Co., Ltd. to acquire 100% equity in Tobishi. The concentration has not yet been implemented to date.

In April 2019, Simcere signed a Cooperation and Supply Agreement with DSM Nutritional Products Ltd Branch Pentapharm (Switzerland) – the sole global supplier of batroxobin active pharmaceutical ingredient (hereinafter referred to as "batroxobin API") – and its affiliates (collectively referred to as "DSM"). This agreement granted Simcere the exclusive right to sell batroxobin API in China's domestic market.

III. Relevant Market

The investigation shows that Simcere is engaged in the sale of batroxobin API, while

Tobishi is engaged in the production and sale of batroxobin injection, establishing a vertical relationship between the two parties. Concurrently, Simcere is developing batroxobin injection, resulting in a horizontal overlap with Tobishi.

(i) Relevant Product Market.

1. Sale of Batroxobin API.

Batroxobin is the generic name designated by the World Health Organization (WHO) for the fibrinogen-coagulating enzyme contained in the venom of Bothrops atrox. There are five subspecies of Bothrops atrox, among which the batroxobin derived from the subspecies Bothrops moojeni exhibits defibrinogenating effects and is used for thrombolysis (also termed "defibrinogenating enzyme"). In contrast, batroxobin from other subspecies demonstrates coagulating properties and is used for hemostasis (also termed "coagulating thrombin"). These two types differ in physicochemical properties, biochemical characteristics, and functions, belonging to separate relevant markets. Batroxobin API belongs to the defibrinogenating enzyme category.

Batroxobin API is primarily used to produce batroxobin injection. From a demand substitutability perspective, pursuant to Article 28 of the Pharmaceutical Administration Law of the People's Republic of China, pharmaceuticals must comply with the Pharmacopoeia of the People's Republic of China and drug standards issued by the medical products administration under the State Council. According to the Pharmacopoeia and the pharmaceutical registration approval documents for batroxobin injection, batroxobin API is the sole active ingredient for producing batroxobin injection; its composition cannot be substituted by any other API. There is no demand substitutability between batroxobin API and other APIs. From a supply substitutability analysis, batroxobin API differs from other APIs in extraction techniques and manufacturing processes. Its extraction technology and generic replication involve high complexity, requiring strictly identified and screened Bothrops atrox snakes. These snakes undergo artificial generational breeding in controlled environments, with venom extracted from the 5th to 7th generations for batroxobin API production. Additionally, market entry for APIs requires clinical testing. Other API manufacturers cannot switch production to supply batroxobin API in the short term. There is no supply substitutability between batroxobin API and other APIs.

As the Case involves the sale of batroxobin API, the relevant product market is defined as the market for batroxobin API sales.

2. Batroxobin Injection.

Batroxobin injection is the exclusive downstream application of batroxobin API in China. It functions as a fibrinogen-reducing drug that decreases fibrinogen concentration in blood, reduces whole blood viscosity and plasma viscosity, lowers vascular resistance, and improves blood flow.

The pharmaceutical is an originator drug developed by Japan Tobishi Pharmaceutical Co., Ltd., produced and supplied in China by Tobishi. It is registered and marketed primarily in Japan and China. In Japan, approved indications include restoration of hearing in sudden deafness and improvement of subjective symptoms, amelioration of peripheral circulatory disorders in vibration disease, and alleviation of ischemic symptoms associated with chronic arterial occlusion. In China, approved indications cover improvement of peripheral/microcirculatory disorders (e.g., sudden deafness, vibration disease), relief of ischemic symptoms caused by various occlusive vascular diseases, and treatment of acute cerebral infarction. Investigations show that the standard medical practice for batroxobin injection primarily involves treating full-frequency hearing loss sudden deafness. For this specific application, batroxobin injection has no viable substitutes, constituting an independent relevant product market.

According to the Guidelines for Diagnosis and Treatment of Sudden Deafness (2015) issued by the Chinese Society of Otolaryngology-Head and Neck Surgery of the Chinese Medical Association, sudden deafness refers to sensorineural hearing loss of unknown etiology that occurs abruptly within 72 hours, with hearing reduction ≥20 dBHL in at least two adjacent frequencies. Based on the affected frequencies and severity, sudden deafness is classified into four types: high-frequency descending, low-frequency descending, flat descending, and total deafness. The flat descending and total deafness types are collectively termed full-frequency hearing loss. Widely recognized pathological mechanisms for full-frequency hearing loss sudden deafness include stria vascularis dysfunction or inner ear vascular spasm, and inner ear vascular embolism or thrombosis.

For full-frequency hearing loss sudden deafness, treatment guidelines and clinical practice

require combined use of: (1) fibrinogen-reducing drugs (e.g., batroxobin injection); (2) corticosteroids; and (3) drugs improving inner ear microcirculation (e.g., ginkgo biloba extract). Investigations confirm that these three drug categories serve distinct pharmacological functions and address different clinical needs. Fibrinogen-reducing drugs cannot be substituted by other categories, nor can other drug manufacturers switch production to supply batroxobin injection in the short term. Thus, batroxobin injection constitutes an independent relevant product market.

The only fibrinogen-reducing drugs approved for the indication of sudden deafness in China are batroxobin injection and Defibrase Injection (or Defibrase for Injection, collectively referred to as Defibrase Injection). While the two exhibit some substitutability, Defibrase Injection does not constitute a close substitute for batroxobin injection based on actual clinical usage needs and product supply conditions.

From a demand substitutability perspective, first, treatment guidelines and medical insurance regulations strongly influence clinical medication choices. The Guidelines for Diagnosis and Treatment of Sudden Deafness (2015) lists only batroxobin injection as the fibrinogen-reducing drugs for treating sudden deafness. Defibrase Injection is not listed. Using batroxobin injection to treat sudden deafness is covered by medical insurance, while using Defibrase Injection for this purpose cannot be reimbursed. Investigations indicate that the aforementioned treatment guidelines and medical insurance regulations have a strong influence on clinical medication choices. Second, batroxobin injection enjoys distinct clinical preference due to medication experience, prescribing habits, and safety profile. Introduced to China in 1993, batroxobin injection has extensive usage experience, and its efficacy has been widely validated in clinical practice over many years. It also has clear administration protocols, facilitating proactive prevention of adverse reactions. Defibrase Injection entered the market in 2003 and has relatively limited clinical use for treating sudden deafness, with less defined administration protocols. Batroxobin injection thus receives significantly greater clinical preference compared to Defibrase Injection. Third, multiple key ENT hospitals indicated that they use batroxobin injection to treat sudden deafness with full-frequency hearing loss and have not used Defibrase Injection. They would only consider Defibrase Injection as a last resort if batroxobin injection were completely unavailable, in order to maximize patient treatment efforts. During the period when the price for batroxobin injection in Beijing

increased from ¥247 to ¥358 per vial, the surveyed hospitals did not switch to using Defibrase Injection for sudden deafness treatment. From a supply substitutability perspective, bringing a new drug formulation to market requires a series of clinical tests and regulatory approvals. Defibrase Injection manufacturers could not readily switch production to supply batroxobin injection in the short term. There is no supply substitutability between batroxobin injection and Defibrase Injection. In summary, batroxobin injection cannot be closely substituted by Defibrase Injection and constitutes a distinct relevant product market.

(ii) Relevant Geographic Market.

Both APIs and finished drugs within China are subject to strict regulation. They must obtain qualifications such as approval documents and Pharmaceuticals Manufacturing Licenses issued by relevant authorities, and meet regulatory requirements including registration testing, expert review, clinical trials, and regular inspections. APIs and finished drugs manufactured overseas require an Import Pharmaceuticals License to be sold in the Chinese market. Obtaining the relevant qualifications and meeting the regulatory requirements takes a considerable amount of time. Therefore, the relevant geographic markets for both batroxobin API sales and batroxobin injection are delineated as within China.

IV. Competitive Analysis

Globally, DSM is the sole manufacturer of batroxobin API. Simcere does not possess the production materials or technology for batroxobin API and lacks the capability to produce it. However, through a Cooperation and Supply Agreement signed with DSM, which stipulates that DSM will exclusively supply batroxobin API to Simcere within China and Simcere has obtained the entire supply of batroxobin API within China and controls the sales market for batroxobin API in China. The only downstream application for this API within China is batroxobin injection. Tobishi is currently the sole manufacturer of batroxobin injection in China, while Simcere is developing batroxobin injection.

Pursuant to Article 33 of the Anti-Monopoly Law, SAMR conducted an in-depth analysis of the impact of this concentration on market competition. This analysis focused on the market share and market control of the undertakings involved in the concentration within the relevant market, the degree of market concentration, and the impact of the concentration on downstream users and other relevant undertakings. It concluded that this concentration may

likely have the effect of eliminating or restricting competition in China's batroxobin injection market.

(i) The concentration may eliminate a potential entrant in China's batroxobin injection market, consolidate Tobishi's dominant position in that market, and have the effect of eliminating or restricting competition.

Tobishi holds a 100% market share in China's batroxobin injection market, giving it a dominant position. Simcere has a batroxobin injection project under development. It has obtained approval to use the originator drug from Japan Tobishi Pharmaceutical Co., Ltd. as the reference listed drug for its generic version, and received drug clinical trial approval in July 2021, making it a potential entrant into China's batroxobin injection market. Investigations reveal that one of the greatest challenges in developing a generic batroxobin injection is the preparation or sourcing of the batroxobin API. As the sole seller of batroxobin API in China, Simcere possesses a unique R&D advantage in accessing the API. Currently, Simcere is the only company in China engaged in developing batroxobin injection. If Simcere's generic drug successfully completes clinical trials and is approved for market entry, it would exert competitive pressure on Tobishi's existing product. The concentration would directly eliminate this potential competitor, consolidate Tobishi's dominant position in China's batroxobin injection market, and may likely have the effect of eliminating or restricting competition.

(ii) The post-concentration entity may engage in input foreclosure, having the effect of eliminating or restricting competition in China's batroxobin injection market.

1. The post-concentration entity has the ability to engage in input foreclosure to eliminate or restrict competition in China's batroxobin injection market.

First, the post-concentration entity holds a dominant position in China's batroxobin API sale market. Through the Cooperation and Supply Agreement signed with DSM, Simcere has obtained the entire supply of batroxobin API within China, making it the only company in the Chinese market that can sell batroxobin API. With a 100% market share in China's batroxobin API sales market, it holds a dominant position. The post-concentration entity will inherit this position.

Second, the post-concentration entity has the ability to control the batroxobin API sales market, and downstream undertakings possess weak bargaining power. After Simcere obtained the entire supply of batroxobin API within China, since batroxobin API is the sole active ingredient for producing the downstream drug batroxobin injection, downstream drug manufacturers can only purchase the API from Simcere. There is no possibility of switching to other suppliers. Consequently, their bargaining power is weak, and they are highly dependent on Simcere and the post-concentration entity.

Third, it is difficult for other undertakings to enter the relevant market. Entry into China's batroxobin API sales market requires a stable supply of the API. DSM is the sole global manufacturer of batroxobin API. After Simcere signed the agreement with DSM, it became difficult for other undertakings to obtain API supply from the manufacturer. Additionally, the production process for batroxobin API is complex, making replication challenging. Other companies would find it difficult to replicate the API or find new supply sources in the short term, resulting in significant barriers to entering the relevant market.

2. The post-concentration entity has the incentive to engage in input foreclosure to eliminate or restrict competition in China's batroxobin injection market.

After generic drugs enter the market, they are typically sold at prices lower than the existing drugs, creating competitive constraints that impact the sales volume and price of the existing drugs. Currently, Tobishi is the sole supplier in China's batroxobin injection market. The post-concentration entity thus has the incentive to foreclose the supply of batroxobin API or raise its supply price to hinder the market entry of other competitors or to secure greater profits.

3. The concentration may likely have the effect of eliminating or restricting competition in China's batroxobin injection market.

The post-concentration entity may eliminate or restrict competition in China's batroxobin injection market through the following input foreclosure: First, it may refuse, restrict, or delay supplying batroxobin API to Tobishi's competitors, hindering their R&D and production. Second, it may implement discriminatory treatment between Tobishi and its competitors, such as prioritizing or exclusively providing related products, technologies, or services to Tobishi, thereby impeding competitors' R&D and production. Third, it may charge competitors

unreasonably high prices for batroxobin API, increasing their R&D and production costs. Upon completion of this concentration, the barriers to entry into the batroxobin injection market will be significantly raised, dampening the incentives for other companies to develop and produce batroxobin injection, and consolidating Tobishi's dominant position in China's downstream batroxobin injection market.

V. Negotiation of Remedies

During the review process, SAMR promptly informed the notifying parties of its preliminary view that the concentration may likely have the effect of eliminating or restricting competition. Multiple rounds of discussions were held with the notifying parties regarding measures to mitigate adverse effects on competition. SAMR evaluated the remedies proposal submitted by Simcere in accordance with the Provisions on the Review of Concentration of Undertakings, focusing on the effectiveness, feasibility, and timeliness of remedies.

Following the evaluation, SAMR determined that the remedy proposal submitted by Simcere on August 25, 2023 (see Appendix) could mitigate the adverse effects of this concentration on competition and lower patient medication costs.

VI. Review Decision

Given that this concentration may likely have the effect of eliminating or restricting competition in China's batroxobin injection market, and based on the remedy proposal submitted by Simcere, SAMR decided to approve this concentration subject to remedies. Simcere and the post-concentration entity were required to fulfill the following obligations (including but not limited to):

First, terminate the exclusive and sole supply agreement between Simcere and DSM for batroxobin API within China.

Second, divest Simcere's ongoing batroxobin injection R&D project within the timeframe stipulated in the Provisions on the Review of Concentration of Undertakings. Undertake the obligation to supply batroxobin API to the divestiture buyer and provide necessary assistance for the divestiture buyer to establish a direct supply relationship with DSM.

Third, after the implementation of the concentration, reduce the end-user price of batroxobin injection in the clinically common specification by no less than 20% of the current

listed price.

Fourth, after the implementation of the concentration, ensure the supply of batroxobin injection in the clinically common specification to meet clinical demand.

Fifth, if the agreement is not terminated on time, the divestiture is not completed on time, or the divestiture buyer fails to proceed with R&D on time, reduce the end-user price of batroxobin injection in the clinically common specification by no less than 50% of the current listed price after the implementation of the concentration.

The supervision and execution of remedies shall be handled in accordance with this announcement. Additionally, the remedies proposal submitted by Simcere to SAMR on August 25, 2023, is legally binding on Simcere and the post-concentration entity.

Six years after the Effective Date of the behavioral remedies, Simcere and the post-concentration entity may apply to SAMR for their removal. SAMR will decide whether to remove these remedies based on the application and market competition conditions. Unless the removal is approved by SAMR, Simcere and the post-concentration entity shall continue to fulfill these remedies.

SAMR has the authority to supervise and inspect the fulfillment of the above obligations by Simcere and the post-concentration entity, either through a supervisory trustee or directly. Should Simcere and the post-concentration entity fail to fulfill the above obligations, SAMR will take action in accordance with relevant provisions of the Anti-Monopoly Law.

This decision takes effect from the date of its announcement.

二、行政复议决定书

先声药业收购托毕西股权案
行政复议决定主要内容

一、案件基本信息

申请人：北京托毕西药业有限公司

被申请人：国家市场监督管理总局

第三人：先声药业有限公司

复议机关：国家市场监督管理总局

由于该复议案件发生于2023年，因此本案适用2017年版《中华人民共和国行政复议法》审理。复议机关于2023年11月13日收到申请人不服被申请人作出的《市场监管总局关于附加限制性条件批准先声药业有限公司收购北京托毕西药业有限公司股权案反垄断审查决定的公告》（2023年第42号，以下简称第42号公告）提出的行政复议申请，并依法予以受理。2023年11月21日，先声药业有限公司申请作为第三人参与复议，复议机关予以批准。经延期审理三十日后，复议机关于2024年2月18日作出了维持第42号公告的复议决定。

二、申请人复议请求

申请人申请撤销被申请人作出的第 42 号公告。申请人认为被申请人作出的第 42 号公告批准第三人收购申请人股权的反垄断审查决定违反了《中华人民共和国反垄断法》（以下简称《反

垄断法》）和《中华人民共和国行政许可法》（以下简称《行政许可法》）的相关规定。

三、复议机关查明的事实

2022 年 6 月 29 日、7 月 20 日，申请人和第三人作为申报人分别向被申请人反垄断机构提交经营者集中申报材料，申报第三人收购申请人股权。经审核，被申请人反垄断机构认为该申报材料不完备，要求双方申报人予以补充。11 月 23 日，被申请人反垄断机构予以立案并开始初步审查，12 月 21 日，决定实施进一步审查，2023 年 3 月 19 日，经双方申报人同意，决定延长进一步审查期限，4 月 25 日，决定中止审查期限，9 月 21 日继续计算审查期限。

审查过程中，被申请人反垄断机构征求有关政府部门、行业协会和相关企业意见，调研医院、专业机构等有关单位，同法律、经济专家深入座谈，了解相关市场界定、市场结构、行业特征和集中对各方面影响等信息，聘请独立第三方机构对本案竞争问题进行经济分析，并对双方申报人提交的文件材料真实性、完整性和准确性进行了审核。

2023 年 9 月 22 日，被申请人作出第 42 号公告。

另外经查，被申请人于 2021 年 1 月 22 日作出“国市监处〔2021〕1 号”处罚，对第三人滥用市场支配地位，拒绝向下游制剂企业销售巴曲酶原料药的行为进行了处罚。

四、复议机关重点审理的问题

（一）本案交易是否违反《反垄断法》第三十四条的规定，并应当予以禁止。复议机关认为，本案所涉交易对中国境内巴曲酶注射液市场存在产生排除、限制竞争效果的可能。但是按照《经营者集中审查规定》，从限制性条件的有效性、可行性和及时性等方面对第三人提交的附加限制性条件承诺方案进行评估，该方案可以减少此项经营者集中对竞争的不利影响，降低患者用药成本。根据《反垄断法》第三十四条规定，加入该附加限制性条件后的本项经营者集中符合法定不予禁止的情形。

（二）限制性条件是否违反《反垄断法》第一条的规定，严重损害竞争。根据《经营者集中审查规定》第四十一条第一款规定，第 42 号公告设置的首选方案和备选方案，被申请人可以依申请并根据市场竞争状况作出是否解除的决定。未经批准解除，第三人和集中后实体应继续履行限制性条件。若届时根据市场竞争状况出现涨价可能，则相关条件不会被解除。因此，该限制性条件不违反《反垄断法》相关规定，并无不当。

（三）本案涉及的交易是否因其他行政处罚决定阻却。经审查，“国市监处〔2021〕1 号”处罚针对的是第三人滥用市场支配地位拒绝交易的违法行为，而本案第 42 号公告涉及的是第三人的经营者集中行为，两者并非同一行为，不存在法律上的关联性。因此，被申请人作出的“国市监处〔2021〕1 号”行政处罚决定，并不妨碍作出第 42 号公告。

（四）被申请人作出的第 42 号公告是否属于行政许可行为

以及是否违反行政许可程序。根据《反垄断法》第二十六条规定，被申请人作出的第 42 号公告具有行政许可属性。同时，第 42 号公告仅对第三人和集中后受第三人控制的申请人施加了义务，相关义务为第三人的主动承诺，未直接涉及其他任何经营主体或第三人与其他经营主体间的关系。第三人取得申请人控制权前，申请人股东子博有限公司不因本行政许可决定承担任何义务。因此，未通知申请人股东子博有限公司参与本次行政许可程序并不违反相关规定。从本案办理程序看，被申请人已于 2022 年 12 月 21 日向第三人、申请人发出《经营者集中反垄断审查实施进一步审查决定书》（反执二审查决定〔2022〕819 号），并就第三人提交的方案全面征求了有关部委、行业协会以及 DSM 和申请人意见。除申请人提出建议禁止意见外，其他单位均无实质性反对意见。2023 年 9 月 22 日，附条件批准决定作出并于同日向社会公布后，于 10 月 8 日（第六个工作日）直接送达第三人和申请人，由其代理人签收。因此，被申请人已经履行相关告知法定程序。

（五）被申请人作出第 42 号公告是否应当履行行政许可听证程序。根据《行政许可法》第四十七条规定，子博有限公司需要将所持有的申请人股权划转给第三人，不是本行政许可施加的义务或造成的影响，而是源于子博有限公司与第三人 2017 年签订的民事合同，该合同为双方真实的意思表示，子博有限公司有出售申请人股权并取得对价的真实意思表示，第三人有取得申请人股权并支付对价的真实意思表示，合同效力受到仲裁认定，强

制执行受到法院支持。第三人与子博有限公司之间为合同权利义务关系，相关合同的效力和强制执行受到仲裁和法院的支持。附加限制性条件决定仅将上述情况作为事实情况予以考虑，未对合同权利义务关系进行变更。因此，第 42 号公告不直接涉及第三人与子博有限公司的利益关系，更不涉及重大利益关系，不符合《行政许可法》规定的“应当告知申请人、利害关系人享有要求听证的权利”的前提条件，无需告知听证权。被申请人已就解除独家协议事项告知第三人和 DSM 享有要求听证等程序性权利。被申请人向 DSM 正式去函告知其听证的权利，并以电话形式告知第三人听证的权利。DSM 和第三人均未要求行使相关权利。因此，被申请人未启动行政许可听证程序并不违反相关规定。

综上，被申请人作出的第 42 号公告认定事实清楚，适用法律正确，符合法定程序。根据《中华人民共和国行政复议法》第六十八条的规定，复议机关作出“国市监复议〔2023〕127 号”复议决定，维持该公告。

II. Administrative Reconsideration Decision

Case of Simcere's Acquisition of Equity in Tobishi

Main Content of the Administrative Reconsideration Decision

I. Basic Information of the Case

Applicant: Beijing Tobishi Pharmaceutical Co., Ltd.

Respondent: State Administration for Market Regulation

Third Party: Simcere Pharmaceutical Co., Ltd.

Reconsideration Authority: State Administration for Market Regulation

As this reconsideration case occurred in 2023, the 2017 Administrative Reconsideration Law of the People's Republic of China applies to its adjudication. The Reconsideration Authority received the Applicant's application for administrative reconsideration on November 13, 2023, against the Respondent's "Announcement of the State Administration for Market Regulation Concerning the Anti-monopoly Review Decision to Approve Subject to Remedies the Acquisition of Equity in Beijing Tobishi Pharmaceutical Co., Ltd. by Simcere Pharmaceutical Co., Ltd." (No. 42, 2023, hereinafter referred to as "Announcement No. 42"), and accepted it according to law. On November 21, 2023, Simcere Pharmaceutical Co., Ltd. applied to participate in the reconsideration as a Third Party, and the Reconsideration Authority approved the application. After a 30-day extension of the hearing period, the Reconsideration Authority issued a reconsideration decision on February 18, 2024, upholding Announcement No. 42.

II. Applicant's Request for Reconsideration

The Applicant applied for the revocation of Announcement No. 42 issued by the Respondent. The Applicant contends that the Anti-monopoly Review Decision in Announcement No. 42, approving the Third Party's acquisition of the Applicant's equity, violated the relevant provisions of the Anti-Monopoly Law of the People's Republic of China (hereinafter referred to as the "Anti-Monopoly Law") and the Administrative License Law of the People's Republic of China (hereinafter referred to as the "Administrative License Law").

III. Facts Ascertained by the Reconsideration Authority

On June 29, 2022, and July 20, 2022, the Applicant and the Third Party, as the notifying parties, respectively submitted materials for the notification of concentration of undertakings to the anti-monopoly agency of the Respondent, notifying the Third Party's acquisition of the Applicant's equity. Upon review, the anti-monopoly agency of the Respondent deemed the notification materials incomplete and requested supplements from the two notifying parties. On November 23, the anti-monopoly agency of the Respondent accepted the case for filing and initiated a preliminary review. On December 21, it decided to implement a further review. On March 19, 2023, with the consent of both notifying parties, it decided to extend the further review period. On April 25, it decided to suspend the review period. On September 21, the calculation of the review period resumed.

During the review process, the anti-monopoly agency of the Respondent solicited opinions from relevant government departments, industry associations, and enterprises; conducted research with hospitals, professional institutions, and other related entities; held in-depth discussions with legal and economic experts to understand information on relevant market definition, market structure, industry characteristics, and the concentration's potential impacts; engaged an independent third-party institution to perform economic analysis on the competition issues of this case; and reviewed the authenticity, completeness, and accuracy of documents and materials submitted by the notifying parties.

On September 22, 2023, the Respondent issued Announcement No. 42.

Additionally, upon investigation, the Respondent issued Penalty Decision No. 1 (2021) on January 22, 2021, penalizing the Third Party for abusing its dominant market position by refusing to sell batroxobin active pharmaceutical ingredient (hereinafter referred to as the “batroxobin API”) to downstream drug manufacturers.

IV. Key Issues Reviewed by the Reconsideration Authority

(i) Whether the transaction in this case violates the provisions of Article 34 of the Anti-Monopoly Law and should therefore be prohibited. The Reconsideration Authority found that the transaction involved in this case may likely have the effect of eliminating or restricting competition in the batroxobin injection market within China. However, following the Provisions on the Review of Concentration of Undertakings, the remedy proposal submitted by the Third Party was assessed in terms of its effectiveness, feasibility, and timeliness. The

proposal could mitigate the adverse impact of this concentration on competition and lower patient medication costs. According to Article 34 of the Anti-Monopoly Law, this concentration, with these remedies, met the statutory circumstances for non-prohibition.

(ii) Whether these remedies violate the provisions of Article 1 of the Anti-Monopoly Law and severely harm competition. In accordance with the provisions of Article 41(1) of the Provisions on the Review of Concentration of Undertakings, the primary and alternative proposals established in Announcement No. 42 can be removed by the Respondent upon application and based on market competition conditions. Without approved removal, the Third Party and the post-concentration entity shall continue to fulfill these remedies. If, at that time, a potential for price increases arises according to market competition conditions, the relevant remedies will not be removed. Therefore, these remedies do not violate the relevant provisions of the Anti-Monopoly Law and are not improper.

(iii) Whether the transaction involved in this case is precluded by another administrative penalty decision. Upon review, the Penalty Decision No. 1 (2021) addresses the illegal act of the Third Party abusing its dominant market position by refusing to trade, whereas Announcement No. 42 in this case pertains to the concentration of undertakings involving the Third Party. These two actions do not constitute the same act and lack legal relevance. Therefore, the Penalty Decision No. 1 (2021) issued by the Respondent does not preclude the issuance of Announcement No. 42.

(iv) Whether Announcement No. 42 issued by the Respondent constitutes an administrative license act and whether it violates administrative license procedures. According to Article 26 of the Anti-Monopoly Law, Announcement No. 42 issued by the Respondent possesses the nature of an administrative license. Simultaneously, Announcement No. 42 imposes obligations only upon the Third Party and the Applicant (controlled by the Third Party post-concentration). These obligations stem from the Third Party's voluntarily committed undertakings and do not directly involve any other business entities or the relationship between the Third Party and other business entities. Prior to the Third Party obtaining control of the Applicant, Zibo Co., Ltd., the Applicant's shareholder, shall not bear any obligations under this administrative license decision. Therefore, not notifying the Applicant's shareholder, Zibo Co., Ltd., to participate in this administrative license procedure did not violate relevant provisions. Regarding the handling procedures of this case, the Respondent had issued the

Decision on Implementing Further Review of the Anti-Monopoly Examination of the Concentration of Undertakings (Review Decision [2022] No. 819) to the Third Party and the Applicant on December 21, 2022, and comprehensively solicited opinions from relevant ministries, industry associations, as well as DSM and the Applicant regarding the proposal submitted by the Third Party. Apart from the Applicant proposing a recommendation for prohibition, no other entities raised substantive objections. On September 22, 2023, the conditional approval decision was made and publicly announced on the same day. It was then served directly to the Third Party and the Applicant on October 8 (the sixth business day), signed for receipt by their agents. Therefore, the Respondent had fulfilled the relevant statutory notification procedures.

(v) Whether the Respondent should have conducted administrative license hearing procedures when issuing Announcement No. 42. According to Article 47 of the Administrative License Law, Zibo Co., Ltd.'s requirement to transfer its equity in the Applicant to the Third Party was not an obligation imposed by or an effect caused by this administrative license. Instead, it originated from the civil contract signed between Zibo Co., Ltd. and the Third Party in 2017. This contract represents the true expression of intent by both parties: Zibo Co., Ltd. genuinely intended to sell the Applicant's equity and receive consideration, and the Third Party genuinely intended to acquire the Applicant's equity and pay consideration. The validity of the contract was confirmed by arbitration, and its enforcement was upheld by the Court. The relationship between the Third Party and Zibo Co., Ltd. is one of contractual rights and obligations, and the validity and enforcement of the relevant contract were supported by arbitration and the Court. The decision to impose remedies merely considered the above situation as a factual circumstance and did not alter the contractual rights and obligations. Therefore, Announcement No. 42 does not directly involve the interests between the Third Party and Zibo Co., Ltd., let alone involve significant interests. It does not meet the precondition stipulated in the Administrative License Law of "informing the applicant and interested parties of their right to request a hearing", and thus there was no need to inform them of the right to a hearing. The Respondent had informed the Third Party and DSM of their procedural rights, including the right to request a hearing, regarding the matter of terminating the exclusive agreement. The Respondent formally notified DSM in writing of its hearing rights and notified the Third Party orally by phone of its hearing rights. Neither DSM nor the

Third Party requested to exercise these rights. Therefore, the Respondent's failure to initiate administrative license hearing procedures did not violate relevant regulations.

In summary, the facts ascertained in Announcement No. 42 issued by the Respondent were clear, the application of law was correct, and the statutory procedures were complied with. In accordance with the provisions of Article 68 of the Administrative Reconsideration Law of the People's Republic of China, the Reconsideration Authority issued Reconsideration Decision No. 127 (2023) upholding the said Announcement.

三、判决书

北京知识产权法院

行 政 判 决 书

（2024）京 73 行初 5180 号

原告：北京某药业公司，住所地北京市海淀区。

法定代表人：余某某。

被告：国家市场监督管理总局，住所地北京市西城区。

法定代表人：罗文。

委托诉讼代理人：赵某某。

委托诉讼代理人：詹某。

第三人：某某药业公司，住所地江苏省南京市。

法定代表人：任某某。

委托诉讼代理人：黄某。

委托诉讼代理人：高某。

原告北京某药业公司与被告国家市场监督管理总局,（简称市场监管总局）、第三人某某药业公司反垄断其他行政行为纠纷一案，本院于 2024 年 3 月 15 日受理后，依法组成合议庭适用普通程序，于 2024 年 9 月 13 日不公开开庭审理了本案。原告北京某药业公司的原委托诉讼代理人杨某、孔某某，被告市场监管总局的委托诉讼代理人赵某某、詹某，第三人某某药业公司的委托诉讼代理人黄某、高某到庭参加诉讼。本案现已审理终结。

2022 年 6 月 29 日、7 月 20 日，市场监管总局先后收到北京某药业公司、某某药业公司提交的某某药业公司收购北京某药业公司股权案经营者集中（简称涉案集中）申报材料，北京某药业公司、某某药业公司后续分别多次补充了相关材料（简称涉案申报材料）。市场监管总局经评估后认为，涉案集中虽未达到申报标准，但可能具有排除、限制竞争效果，故于 2022 年 11 月 23 日立案审查。市场监管总局经审查认为，虽然涉案集中对中国境内巴曲酶注射液市场可能具有排除、限制竞争效果，但是某某药业公司于 2023 年 8 月 25 日提交的附加限制性条件承诺方案（简称承诺方案）可以有效减少涉案集中对竞争的不利影响，符合《中华人民共和国反垄断法》（简称反垄断法）等相关法律法规关于附条件批准的情形，因此，市场监管总局作出 2023 年第 XX 号决定（简称被诉决定），附加限制性条件批准涉案集中，并于 2023 年 9 月 22 日公告。

北京某药业公司不服被诉决定，于法定期限内向市场监管总局申请行政复议。2023 年 11 月 21 日，某某药业公司申请作为第三人参与复议，市场监管总局予以批准。

2024 年 2 月 18 日，市场监管总局作出国市监复议〔2023〕XXX 号行政复议决定（简称被诉复议决定），决定：维持被诉决定。

北京某药业公司不服被诉决定和被诉复议决定，向本院提出诉讼请求：1.撤销被诉决定；2.撤销被诉复议决定。事实与理由：

1.被诉决定严重违反《中华人民共和国行政许可法》（简称行政许可法）规定的法定听证程序、没有向利害关系人某博有限公司履行法定告知义务、严重损害某博有限公司的听证权利。2.被诉决定与被诉复议决定认定事实错误。某某药业公司是在北京某药业公司向市场监管总局申报后由市场监管总局通知申报，不属于自愿申报。3.被诉决定和被诉复议决定适用法律错误。（1）涉案集中本身就是必须直接禁止的交易，基于以下理由：第一，反垄断法对于排除、限制竞争的经营者集中以禁止为法定和首选的救济方式，仅在特殊条件下才适用附加限制性条件批准。第二，本案涉及巴曲酶注射液市场仅有的两个竞争者之间的并购，且集中后会导致独占性垄断，严重损害竞争。第三，某某药业公司通过垄断原料药的方式进行涉案集中曾被市场监管总局认定是拒绝交易的滥用市场支配地位行为。（2）承诺方案存在重大漏洞，不能有效减少对竞争的不利影响，不能据此作出附加限制性条件批准，具体理由为：第一，北京某药业公司提交的经济学者意见证明承诺方案带来的价格降低幅度远远低于竞争所带来的价格降低幅度，可能实际提高巴曲酶注射液的价格，形成独占性垄断，阻碍竞争。第二，备选方案给了某某药业公司独占市场的机会，可能导致巴曲酶注射液的产量减少、质量下降、供给不及时。且承诺方案允许某某药业公司以简单降低价格作为剥离条件的备选方案，使得国务院反垄断执法机构从市场竞争的维护者变为价格监管者。第三，某某药业公司可以通过操纵原料药成本上升和供应

不足最终实现提价目的。第四，某某药业公司可以采取相关措施，人为地使巴曲酶注射液被列入短缺药清单，从而规避20%的价格承诺要求。此外，承诺方案还规定了“因某某药业公司不可控制的因素导致的意外”，可以作为违反“避免发生托毕西巴曲酶注射液被列入国家短缺药品清单、临床必需易短缺药品终端监测清单”承诺的例外。市场监管总局作出的国市监处〔2021〕X号行政处罚决定（简称X号行政处罚决定）可佐证某某药业公司可以“人为”影响DSM库存情况，通过断货而逃避监管。第五，承诺方案中“尽商业上的合理努力”条款，监管标准不清，不具有可监管性。第六，被诉决定作出以后的一年内，某某药业公司并没有按照承诺方案进行剥离，实际实现了独占市场的目的。此外，仲裁结果和专家咨询意见均不应影响本案审查。

市场监管总局辩称：北京某药业公司并非本案适格原告，且被诉决定和被诉复议决定认定事实清楚，适用法律法规正确，审查程序合法，北京某药业公司的诉讼理由不能成立。因此，请求依法裁定驳回北京某药业公司的起诉或判决驳回其全部诉讼请求。

某某药业公司述称：市场监管总局作出被诉决定和被诉复议决定的证据确凿，适用法律正确，符合法定程序，北京某药业公司的诉讼请求缺乏事实和法律依据，应裁定驳回北京某药业公司的起诉或者判决驳回北京某药业公司的全部诉讼请求。

本案诉讼中，北京某药业公司、市场监管总局、某某药业公

司围绕诉讼理由、答辩意见、陈述意见依法提交了证据，本院组织各方进行了证据交换和质证。

本院经审理查明如下事实:

一、北京某药业公司股权收购相关事实

北京某药业公司于 1993 年在北京市设立，该公司股权持有人某博有限公司在中国香港设立，最终控制人为自然人。北京某药业公司从事巴曲酶注射液生产和销售，是目前中国境内唯一具有巴曲酶注射液生产资质和生产能力的企业。

某某药业公司于 1998 年在江苏省南京市设立，母公司某某药业集团有限公司（简称某某药业集团）在中国香港设立，于香港联合交易所上市，最终控制人为自然人。某某药业公司及其关联方（以下统称为某某药业方）主要从事药品生产和销售。某某药业方正在研发巴曲酶注射液。

2016 年 6 月，周某某担任法定代表人的大某林公司经全球巴曲酶浓缩液原料药（简称巴曲酶原料药）唯一供应商瑞士 DSM Nutritional Products Ltd Branch Pentapharm（本判决将该公司与其关联方统称为 DSM）授权，取得巴曲酶原料药中国境内的独家代理权。同年 12 月，北京某药业公司法定代表人变更为周某某。

2017 年 7 月 21 日，某某药业方与某博有限公司签订《股权转让协议》（简称集中协议），拟收购北京某药业公司全部股权。

2019 年 3 月 27 日，江西普元健康产业有限公司（简称普元公司）与周某某就收购北京某药业公司、某博有限公司 100%股权

签订协议书，并于 2019 年 4 月 22 日签订控制权交接确认单，2019 年 5 月 15 日北京某药业公司的法定代表人和董事会成员依据股权收购协议书完成变更。

2019 年 4 月 29 日，某某药业方与 DSM 签订《合作及供货协议》，成为中国境内市场唯一可以销售巴曲酶原料药的公司。

2019 年 7 月 25 日，某某药业方以某博有限公司等为被申请人，基于某博有限公司违反集中协议为由，请求某博有限公司等支付违约金 5000 万元。2020 年 3 月 27 日，上海国际经济贸易仲裁委员会作出仲裁裁决，支持了某某药业方请求某博有限公司支付违约金 5000 万元的主张。

2020 年 9 月，北京某药业公司向市场监管总局举报某某药业方拒绝向北京某药业公司供应巴曲酶原料药等行为涉嫌滥用市场支配地位。

市场监管总局于 2021 年 1 月 22 日作出 1 号行政处罚决定，认定某某药业方的行为构成拒绝交易的滥用市场支配地位行为，责令某某药业方停止违法行为，并处 2019 年度销售额 50.367 亿元 2%的罚款，共计 1.007 亿元。

2021 年 4 月 7 日，某某药业方再次以某博有限公司等为被申请人提起仲裁申请，请求某博有限公司继续履行集中协议，将其对北京某药业公司的 100%股权转让给某某药业方。2022 年 1 月 18 日，上海国际经济贸易仲裁委员会作出[2022]沪贸仲裁字第 0195 号裁决（简称 195 号裁决）认定，某某药业方与某博有限公

司于 2017 年签署的集中协议合法有效，对双方当事人具有法律约束力，双方当事人应按照合同约定履行义务，故支持了某某药业方要求股权转让的请求。

某博有限公司不服 195 号裁决向上海市第二中级人民法院申请撤销仲裁裁决。2022 年 8 月，上海市第二中级人民法院裁定驳回某博有限公司的申请。后，某博有限公司又向北京市第一中级人民法院申请不予执行仲裁裁决。2023 年 8 月，北京市第一中级人民法院裁定驳回某博有限公司提出的不予执行仲裁裁决的申请。

普元公司不服 195 号裁决，向北京市第一中级人民法院申请不予执行仲裁裁决和中止执行仲裁裁决。2023 年 2 月、4 月，北京市第一中级人民法院分别裁定驳回普元公司提出的不予执行仲裁裁决申请和中止执行仲裁裁决申请。普元公司不服上述裁定，向北京市高级人民法院申请复议。2023 年 6 月，北京市高级人民法院裁定驳回普元公司提出的复议申请，维持北京市第一中级人民法院作出的上述裁定。

2024 年 4 月 7 日，北京市第一中级人民法院作出（2023）京 01 执恢 256 号执行裁定，裁定北京某药业公司 100%股权变更登记至某某药业公司名下。

2024 年 4 月 9 日，某某药业公司根据《中华人民共和国公司法》等相关法律规定及公司章程作出股东决定，免去熊国庆、程军、余恕林、熊国煌、王艳坤、陈燕怡等人的董事及监事职务，

同时委派余庆祝、杨杨、唐天桂、茅婷婷、王丹丹、侯志伟等人担任北京某药业公司董事及监事，其中余庆祝任董事长及法定代表人。

某博有限公司以195号裁决履行期限不明确、某某药业方尚未支付股权转让款等为由，向北京市第一中级人民法院申请将北京某药业公司股权执行回转至某博有限公司名下。2024年4月25日，北京市第一中级人民法院裁定驳回某博有限公司的申请。某博有限公司不服，向北京市高级人民法院申请复议。2024年6月18日，北京市高级人民法院裁定驳回某博有限公司的复议申请。

2024年7月10日，江西省赣州市章贡区人民法院基于江西普庆医药有限公司的申请，作出诉前行为保全裁定，禁止北京某药业公司办理法定代表人的工商变更、备案登记。

2024年12月9日，中华人民共和国最高人民法院作出（2024）最高法知民终702号上诉人北京某药业公司与上诉人某某药业集团有限公司、江苏某某药业公司拒绝交易纠纷二审民事裁定，该裁定认定:“本案争议现实际发生在北京某药业公司与其独资股东某某药业公司以及某某药业集团有限公司、江苏某某药业公司之间，以上主体均为关联公司，都已知悉某某药业公司作出股东决议变更北京某药业公司法定代表人为余庆祝的事实，均非对此不知情的‘善意相对人’。因此，在本案中应当以某某药业公司作为北京某药业公司的唯一股东所作出的股东决议为准，认定北京某药业公司的法定代表人已经变更为余庆祝，余庆祝代表北京某药业

公司撤回上诉应认定为该公司的真实意思表示。北京某药业公司在本案审理期间提出撤回上诉的请求不违反法律规定，某某药业集团有限公司、江苏某某药业公司在本案审理期间提出撤回上诉的请求亦不违反法律规定，予以准许。”

上述裁定作出后，北京某药业公司法定代表人余庆祝表示不需要再次开庭，不提交书面意见，请求法院依法作出裁判。

二、涉案集中申报相关事实

2022 年 6 月 29 日、7 月 20 日，北京某药业公司、某某药业公司分别向市场监管总局提交经营者集中申报材料。

2022 年 11 月 23 日，市场监管总局依法对涉案集中申报作出立案通知书，并于次日向某某药业公司、北京某药业公司送达。

2022 年 12 月 21 日，市场监管总局依法作出实施进一步审查决定书，并于同日向某某药业公司、北京某药业公司送达。

2023 年 3 月 17 日，市场监管总局向某某药业公司、北京某药业公司通报涉案集中对中国境内巴曲酶注射液市场可能具有排除、限制竞争的竞争关注，并要求申报人提出附加限制性条件承诺方案，告知可在 10 个工作日内提交书面申辩意见。某某药业公司表示尽快提交承诺方案，北京某药业公司认同竞争关注，并继续提交意见。

2023 年 3 月 19 日，经某某药业公司、北京某药业公司同意，市场监管总局决定延长进一步审查期限，涉案集中审查期限延长至 2023 年 5 月 17 日，并于 2023 年 3 月 19 日向某某药业公司、

北京某药业公司送达。

2023 年 4 月 25 日，市场监管总局作出中止计算审查期限的决定，并于 2023 年 9 月 21 日继续计算审查期限，相关决定分别于 2023 年 4 月 25 日、2023 年 9 月 21 日向某某药业公司、北京某药业公司送达。

市场监管总局在对涉案集中进行审查的过程中，向行业主管机构等相关主体书面征求意见。行业主管机构、行业协会与相关主体均未对涉案集中提出反对意见，部分主体建议要求企业承诺收购后巴曲酶注射液产品的终端价格保持相对稳定，同时后续如有其他企业的巴曲酶产品获批，某某药业公司在供应原料药时，应公平对待各家企业。

市场监管总局调研了北京各医院等一线单位。各医院普遍反映巴曲酶注射液在全频听力下降型突发性聋的治疗方面具有难以替代的作用，未使用过降纤酶注射液等。国家药品监督管理局药品审评中心介绍了药品审批适用症与临床使用的差异，并介绍了巴曲酶注射液研发的难点和蛇毒类药品已多年未获批的客观情况。

市场监管总局聘请独立第三方机构对涉案集中开展第三方经济学分析。经济学分析发现，当前纵向双重垄断的市场结构效率过于低下，如果某某药业公司并购北京某药业公司，巴曲酶原料药转为内部供应，避免某某药业公司向北京某药业公司供货时的加价环节，存在减轻价格加成、提高市场供应效率的空间。但

是并购后形成的纵向一体化市场效率仍较低，提升的效率能否传递至消费者难以确定。第三方机构对附加的限制性条件提出了建议。

2023 年 4 月 13 日，市场监管总局组织召开专家咨询会，专题研讨案件处理方式。专家一致认为，本案与此前滥用市场支配地位案涉及两个不同行为，建议以附加限制性条件方式结案。

2023 年 4 月起，某某药业公司提交多版本承诺方案及说明函。

2023 年 7 月 10 日，市场监管总局就某某药业公司 2023 年 7 月 10 日提交的承诺方案征求了有关主管部门、行业协会、DSM、北京某药业公司等相关主体的意见。部分回函中提出：建议企业在后续实施生产过程中，需保障临床常用规格（0.5ml:5BU）巴曲酶注射液供应。除北京某药业公司表示建议禁止外，其他单位对承诺方案均无意见。

随后，某某药业公司进一步修改了承诺方案，并于 2023 年 8 月 25 日提交了最终版承诺方案。某某药业公司和集中后实体承诺如下主要内容:

一是解除某某药业公司与 DSM 在中国境内独家、排他供应巴曲酶原料药的协议约定。自解除独家日后，某某药业公司不得与 DSM 就巴曲酶原料药在中国境内达成独家或排他供应约定。除为满足某某药业公司生产北京某药业公司巴曲酶注射液所需巴曲酶原料药，保障关键岗位人员完成变更日前北京某药业公司巴曲酶注射液生产合理所需巴曲酶原料药，以及向剥离买方提供

的过渡性服务外，某某药业公司不享有巴曲酶原料药的转售权利。同时，某某药业公司不得限制剥离买方和关键岗位人员完成变更日前的北京某药业公司直接向DSM或其他方采购巴曲酶原料药。

二是按照《经营者集中审查规定》规定的时限剥离某某药业公司在研巴曲酶注射液业务。向剥离买方承担巴曲酶原料药供应义务，优先供应剥离买方继续研发先声药业自研巴曲酶注射液所需巴曲酶原料药。若剥离买方继续研发的先声药业自研巴曲酶注射液获批上市，不得拒绝向剥离买方供应巴曲酶原料药，但因先声药业不可控制的因素导致的除外。尽商业上的合理努力，在剥离买方的配合下，协助剥离买方就先声药业自研巴曲酶注射液临床试验许可在临床试验信息登记平台进行申办者变更。尽商业上的合理努力为剥离买方与DSM达成直接供应关系提供必要协助。

三是自关键岗位人员完成变更日起下调临床常用规格的巴曲酶注射液终端价格不少于当前挂网价格的20%。仅在汇率、原材料价格变化导致的生产成本上涨的情况下，可对北京某药业公司巴曲酶注射液挂网价格进行合理上调，但上调幅度不得超过生产成本的实际上涨。

四是自关键岗位人员完成变更日起保障临床常用规格的巴曲酶注射液用药需求，避免发生北京某药业公司巴曲酶注射液被列入国家短缺药品清单、临床必需易短缺药品重点监测清单的情况，但因某某药业公司不可控制的因素导致的除外。

五是若未按时解除协议约定、未按时完成剥离或者剥离买方

未按时实施研发，集中实施后下调临床常用规格的巴曲酶注射液终端价格不少于当前挂网价格的50%,某某药业公司仅可因汇率、原材料价格变化导致的生产成本上涨，对北京某药业公司巴曲酶注射液挂网价格进行合理上调，但上调幅度不得超过生产成本的实际上涨。

限制性条件的监督执行除按公告办理外，承诺方案对某某药业公司和集中后实体具有法律约束力。

行为性条件自生效日起6年后，市场监管总局将依申请并根据市场竞争状况作出是否解除的决定。未经市场监管总局批准解除，某某药业公司和集中后实体应继续履行限制性条件。

市场监管总局有权通过监督受托人或自行监督检查某某药业公司和集中后实体履行上述义务的情况。某某药业公司和集中后实体如未履行上述义务，市场监管总局可根据反垄断法相关规定作出处理。

三、被诉决定、被诉复议决定内容

2023年9月22日，市场监管总局作出被诉决定，并于当日向社会公布。随后，向某某药业公司、北京某药业公司送达。

被诉决定内容如下：某某药业公司从事巴曲酶原料药销售，北京某药业公司从事巴曲酶注射液生产与销售，二者存在纵向关系。同时，某某药业公司正在从事巴曲酶注射液研发，与北京某药业公司存在横向重叠。涉案集中涉及到中国境内的巴曲酶原料药销售市场和巴曲酶注射液市场，可能对中国境内巴曲酶注射液

市场产生排除、限制竞争效果。一方面，集中可能消除中国境内巴曲酶注射液市场潜在进入者，巩固北京某药业公司在该市场的支配地位，产生排除、限制竞争效果。另一方面，集中后实体可能实施原料封锁，对中国境内巴曲酶注射液市场产生排除、限制竞争效果。巴曲酶注射液是一种降低纤维蛋白原药物，在全频听力下降突发性聋的治疗上难以被其他药品替代。审查过程中，市场监管总局将本案可能具有排除、限制竞争效果的审查意见告知申报方某某药业公司，并与申报双方就如何减少此项经营者集中对竞争的不利影响等有关问题进行了多轮商谈。对某某药业公司提交的附加限制性条件承诺方案，市场监管总局重点从限制性条件的有效性、可行性和及时性方面进行了评估后认为，某某药业公司于2023年8月25日提交的附加限制性条件承诺方案可以减少此项经营者集中对竞争的不利影响，并降低患者用药成本。

鉴于此项经营者集中在中国境内巴曲酶注射液市场可能具有排除、限制竞争效果，市场监管总局决定附加限制性条件批准此项集中。

被诉决定自公告之日起生效。作为被诉决定公告的附件，向社会公布的某某药业公司于2023年8月25日提交的承诺方案，与被诉决定同日生效。

2023年11月13日，市场监管总局法制机构收到北京某药业公司不服被诉决定提出的行政复议申请，并予以受理。

2024年2月18日，市场监管总局作出被诉复议决定，认为

被诉决定认定事实清楚，适用法律正确，符合法定程序，决定予以维持。2024 年 2 月 22 日，市场监管总局向北京某药业公司送达了被诉复议决定。

以上事实，有申报材料、补充材料、X 号行政处罚决定、承诺方案及说明函、被诉决定、被诉复议决定、研究报告、合作及供货协议、沟通记录、临床批件、招股说明书、巴曲酶注射液说明书、情况说明、经济学评估报告、专家意见及补充意见、民事判决书、仲裁裁决书、邮件及邮件记录、付款凭证、发票、通知书、决定书，以及当事人陈述等在案佐证。

本院认为：综合各方当事人诉讼理由、答辩意见和陈述意见，本案具有以下五个争议焦点：一是北京某药业公司是否为本案的适格原告；二是被诉决定的作出是否存在程序违法情形；三是被诉决定是否存在认定事实错误；四是市场监管总局对涉案集中以附加限制性条件方式予以批准是否合法；五是市场监管总局采纳某某药业公司提出的承诺方案作为批准涉案集中所附加的限制性条件是否合法。

一、关于北京某药业公司是否为本案的适格原告

《中华人民共和国行政诉讼法》（简称行政诉讼法）第二十五条第一款规定，行政行为的相对人以及其他与行政行为有利害关系的公民、法人或者其他组织，有权提起诉讼。《最高人民法院关于适用〈中华人民共和国行政诉讼法〉的解释》第六十九条第一款第八项规定，有下列情形之一，已经立案的，应当裁定驳

回起诉：（八）行政行为对其合法权益明显不产生实际影响的。市场监管总局针对经营者集中申报作出的具体行政行为的性质为行政许可。在此基础上，如针对经营者集中申报作出的是不予禁止的决定，由于该具体行政行为对于各申报人而言均未变更或增加其基于集中协议而产生的权利义务关系，即未影响其合法权益，故各申报人均无提起行政诉讼的诉的利益。如作出的是禁止的决定或附加限制性条件批准的决定，由于该具体行政行为否定了各申报人基于集中协议而产生的权利义务关系，或对集中后的申报人施加了法定义务，即影响到相应申报人的合法权益，故相应申报人具有提起行政诉讼的诉的利益。

具体到本案，被诉决定系附加限制性条件批准决定，且所附限制性条件系申报一方某某药业公司提出的承诺方案，而非另一申报方北京某药业公司所提，故被诉决定所附加的限制性条件实质上会给集中后的北京某药业公司施加法定义务，对北京某药业公司的合法权益产生实际影响。据此，北京某药业公司具有提起本案行政诉讼的诉的利益，系本案适格原告。市场监管总局、某某药业公司的相关主张，缺乏法律依据，本院不予支持。

二、关于被诉决定的作出是否存在程序违法情形

行政许可法第四十七条规定，行政许可直接涉及申请人与他人之间重大利益关系的，行政机关在作出行政许可决定前，应当告知申请人、利害关系人享有要求听证的权利；申请人、利害关系人在被告知听证权利之日起五日内提出听证申请的，行政机关

应当在二十日内组织听证。

本案中，北京某药业公司主张应当享有听证权利的某博有限公司不属于上述法律规定的应被告知主体。

一方面，从被诉决定是否涉及某博有限公司与某某药业公司的关系角度分析，某某药业公司与某博有限公司之间为合同权利义务关系，属于民事法律关系，相关合同的效力和强制执行由仲裁裁决和法院裁判文书规范。而被诉决定仅将上述情况作为事实情况予以考虑，并未创设或改变双方合同权利义务关系。因此，被诉决定并不涉及某某药业公司与某博有限公司之间的利益关系，更不涉及其双方之间的重大利益关系。

另一方面，从某博有限公司与被诉决定的相关性角度分析，被诉决定仅对某某药业公司和集中后受某某药业公司控制的北京某药业公司施加了义务，相关义务未直接涉及某博有限公司与某某药业公司或者北京某药业公司之间的关系。需要强调的是，某博有限公司需要将所持有的北京某药业公司股权划转给某某药业公司，并不是被诉决定施加的义务或造成的影响，而是基于某博有限公司与某某药业公司基于意思自治而达成的集中协议。因此，北京某药业公司所主张的某博有限公司所受到的影响与被诉决定不具有直接相关性。

此外，北京某药业公司所声称的“某某药业公司在没有支付任何对价的情况下强行对于北京某药业公司的全部股权进行了工商登记变更”，涉及的是双方之间的民事法律关系，应该由人民法

院或者仲裁机构处理，与具有行政许可性质的被诉决定无关，与本案涉及的行政法律关系也无关，更无法证明某博有限公司应当就被诉决定的作出享有听证权利。因此，对北京某药业公司相关主张，本院不予评述。

市场监管总局在法定期限内履行了告知、送达等法定程序，保障了北京某药业公司的程序性权利，作出被诉决定的行政程序合法正当。北京某药业公司关于被诉决定作出程序违法的主张，缺乏事实和法律依据，本院不予支持。

三、关于被诉决定是否存在认定事实错误

某某药业公司收购北京某药业公司股权案因北京某药业公司未达到营业额标准，在市场监管总局未书面正式要求申报的情况下，某某药业公司于涉案集中实施前向市场监管总局进行自愿申报，符合相关规定，被诉决定对此认定并无不当。北京某药业公司关于被诉决定认定事实有误的主张不能成立，本院不予支持。

四、关于市场监管总局对涉案集中以附加限制性条件方式予以批准是否合法

市场监管总局对涉案集中具有作出附加限制性条件批准决定的职权。反垄断法第二十六条第一款规定，经营者集中达到国务院规定的申报标准的，经营者应当事先向国务院反垄断执法机构申报，未申报的不得实施集中。经营者集中未达到国务院规定的申报标准，但有证据证明该经营者集中具有或者可能具有排除、限制竞争效果的，国务院反垄断执法机构可以要求经营者申报。

同时，《经营者集中审查暂行规定》第十六条规定，经营者集中未达到申报标准，参与集中的经营者自愿提出经营者集中申报，市场监管总局收到申报文件、资料后经审查认为有必要立案的，应当按照反垄断法予以立案审查并作出决定。

《经营者集中审查暂行规定》依据反垄断法制定，且第十六条规定应“按照反垄断法予以审查”，则在经营者集中未达到申报标准情况下时，“自愿申报”与反垄断法上有明确规定的“要求申报”的审查标准理应相同。

反垄断法第三十四条规定，经营者集中具有或者可能具有排除、限制竞争效果的，国务院反垄断执法机构应当作出禁止经营者集中的决定。但是，经营者能够证明该集中对竞争产生的有利影响明显大于不利影响，或者符合社会公共利益的，国务院反垄断执法机构可以作出对经营者集中不予禁止的决定。反垄断法第三十五条规定，对不予禁止的经营者集中，国务院反垄断执法机构可以决定附加减少集中对竞争产生不利影响的限制性条件。

本案中，涉案集中涉及某某药业公司收购北京某药业公司的全部股权，属于反垄断法规定的经营者集中。尽管涉案集中未达到经营者集中申报标准，但根据反垄断法第二十六条、《经营者集中审查暂行规定》第十六条规定，市场监管总局具有对涉案集中进行反垄断审查的职权。根据反垄断法、《经营者集中审查规定》有关规定，对于具有或者可能具有排除、限制竞争效果的经营者集中，市场监管总局可以根据案件情况作出不予禁止、附条

件批准、禁止等不同类型的决定，对涉案集中具有作出附加限制性条件批准决定的职权。

根据在案事实可知，某某药业方通过与 DSM 签订《合作及供货协议》，取得中国境内巴曲酶原料药的全部货源，控制中国境内巴曲酶原料药销售市场。该原料药在中国境内唯一下游应用为巴曲酶注射液，北京某药业公司是目前中国境内巴曲酶注射液唯一生产商，某某药业方正在研发巴曲酶注射液。因而，某某药业公司与北京某药业公司既在巴曲酶注射液市场存在横向重叠，又在巴曲酶原料药销售市场存在纵向关系。鉴于巴曲酶注射液是一种降低纤维蛋白原药物，在全频听力下降突发性聋的治疗上难以被其他药品替代，故涉案集中涉及到中国境内的巴曲酶原料药销售市场和巴曲酶注射液市场，可能对中国境内巴曲酶注射液市场产生排除、限制竞争效果。一方面，集中可能消除中国境内巴曲酶注射液市场潜在进入者，巩固北京某药业公司在该市场的支配地位，产生排除、限制竞争效果。另一方面，集中后实体可能实施原料封锁，对中国境内巴曲酶注射液市场产生排除、限制竞争效果。

北京某药业公司基于对具有或可能具有排除、限制竞争的集中“禁止为法定和首选的救济方式”的理解，结合涉案集中具体情况，认为“本次集中本身就是必须直接禁止的交易”。市场监管总局则认为，对具有或可能具有排除、限制竞争效果的经营者集中，禁止集中不是首选救济方案，在经营者能提出有效承诺方案的情

况下可以附加限制性条件批准，本次涉案集中也不属于必须禁止的情形。对此，本院认为：

首先，从法律法规的规定看，反垄断法虽规定了经营者集中审查制度，但反垄断法第六条规定，经营者可以通过公平竞争、自愿联合，依法实施集中，扩大经营规模，提高市场竞争能力。可知，反垄断法明确了对经营者集中的“例外干预”原则。同时反垄断法第三十四条、第三十五条也没有将禁止作为法定和首选的救济方式，而是规定“对不予禁止的经营者集中，国务院反垄断执法机构可以决定附加减少集中对竞争产生不利影响的限制性条件”。对于反垄断法第四章中的具体规定，应当结合反垄断法第六条“例外干预”原则理解，不能割裂地机械解读。《经营者集中审查规定》第三十九条第一款和第二款进一步规定，“为减少集中具有或者可能具有的排除、限制竞争的效果，参与集中的经营者可以向市场监管总局提出附加限制性条件承诺方案。市场监管总局应当对承诺方案的有效性、可行性和及时性进行评估，并及时将评估结果通知申报人”。可见，对于具有或者可能具有的排除、限制竞争的效果的经营者集中，市场监管总局并非应当然直接禁止。参与集中的经营者可以提出附加限制性条件承诺方案，而市场监管总局应当对该方案予以评估，如果评估认为承诺方案不能有效减少集中对竞争产生的不利影响，市场监管总局才应作出禁止经营者集中的决定。北京某药业公司认为“反垄断法对于具有排除、限制竞争效果的经营者集中以禁止为法定和首选的救济方式，而

仅在特殊条件下才适用附加限制性条件批准通过”系对反垄断法理解有误，其相关诉讼主张缺乏法律依据，本院不予支持。

其次，从经营者集中反垄断审查的目的看，“经营者集中具有或者可能具有排除、限制竞争效果”指的是“由集中本身带来的竞争问题”。经营者集中审查执法的目的，主要是解决因集中而产生的竞争问题，而非解决集中前已经存在的竞争问题。具体到本案中，巴曲酶注射液市场当下的竞争状况并非经营者集中审查所关注的。退一步讲，即使考虑北京某药业公司的主张，从竞争结构的竞争者数量看，集中前后，相关市场亦均存在一个既存竞争者和一个潜在进入者，即禁止集中和附加限制性条件批准集中两种情形下市场竞争者数量并无不同。并且，如前所述，如承诺方案能够解决由涉案集中本身带来的竞争问题，有效减少集中对竞争可能产生的不利影响，则市场监管总局可以作出附加限制性条件批准决定。

最后，市场监管总局对于某某药业公司作出的 1 号行政处罚决定，系针对某某药业公司在中国境内巴曲酶原料药销售市场的拒绝交易行为的行政处罚。而被诉决定则是对某某药业公司收购北京某药业公司股权行为是否可能产生排除、限制竞争效果进行审查后的行政许可，两者性质不同。加之，涉案集中所基于的某某药业方与某博有限公司于 2017 年签署的集中协议，也非因滥用市场支配地位行为胁迫而订立，集中协议的效力已经为相关仲裁机构、人民法院的仲裁和裁判文书所确认，进一步证明了北京

某药业公司所主张的“集中协议之签署属于前述滥用市场支配地位行为的具体表现形式或直接后果”不能够成立。需强调的是，经营者集中审查是对某项交易是否具有或者可能具有排除、限制竞争效果进行事前的审查判断，交易最后是否实际实施，与经营者集中审查决定无关。在经营者集中审查中，市场监管总局没有义务也无需对集中协议的有效性进行实质审查。如果交易双方对于集中协议的效力有争议，应当由仲裁机构或人民法院根据法律规定和协议约定予以确认。综上，某某药业公司是否被认定实施拒绝交易的滥用市场支配地位行为，与涉案集中审查无关，更无法证明涉案集中因此须被直接禁止。

综上所述，市场监管总局对涉案集中以附加限制性条件方式予以批准合法，北京某药业公司的相关诉讼主张，均缺乏事实和法律依据，本院不予支持。

五、关于市场监管总局采纳某某药业公司提出的承诺方案作为批准涉案集中所附加的限制性条件是否合法

涉案集中审查时《经营者集中审查规定》已生效。该规定第三十九条第二款规定，市场监管总局应当对承诺方案的有效性、可行性和及时性进行评估。第四十二条第一款规定，对于具有或者可能具有排除、限制竞争效果的经营者集中，参与集中的经营者提出的附加限制性条件承诺方案能够有效减少集中对竞争产生的不利影响的，市场监管总局可以作出附加限制性条件批准决定。由此可知，通过对承诺方案有效性、可行性和及时性的评估，

市场监管总局认为该方案能够有效减少集中对竞争产生的不利影响，市场监管总局可以据此作出附加限制性条件批准决定。

本案中，北京某药业公司主张承诺方案存在重大漏洞，不能有效减少对竞争的不利影响。对此本院认为，北京某药业公司的相关理由缺乏依据。结合北京某药业公司的具体主张，本院分析如下:

（一）附加限制性条件具有有效性。

首先，从实施巴曲酶原料药封锁的关注分析，某某药业公司和集中后实体承诺解除独家协议约定，能够从源头消除某某药业公司实施原料封锁的能力，并且恢复中国境内各方向 DSM 采购巴曲酶原料药的开放性，有利于减少中间环节，提高经济效率。同时，除自用、保障过渡期间北京某药业公司生产和履行向剥离买方供应义务外，禁止某某药业公司和集中后实体享有转售权，可以防止变相形成原料独家销售权。因而，承诺方案能够消除某某药业公司实施原料封锁的能力。

其次，从涉案集中效率提升的传递分析，某某药业公司和集中后实体承诺，完成关键岗位人员变更后保障临床常用规格用药需求,并且下调向医疗机构的销售价格不少于当前挂网价格20%。集中带来的效率提升能够减少患者支出，同时节约医保资金。即承诺方案可保障消除双重加价的效率提升传递到消费者。此外，承诺方案明确，某某药业公司将保障临床常用规格的巴曲酶注射液用药需求，避免该药品被列入国家短缺药品清单、临床必需易

短缺药品重点监测清单，且仅能根据汇率、原材料价格变化导致的生产成本上涨对巴曲酶注射液挂网价格进行合理上调，并且上调幅度不得超过生产成本的实际上涨。即某某药业公司不得因巴曲酶注射液列入短缺药品清单而上调价格。同时，无充分证据证明某某药业公司具有操纵原料药成本上升的能力。此外，承诺方案的履行受到市场监管总局和监督受托人的严格监督。在严格的监督程序下，对于相关情形是否属于“因先声药业不可控制的因素导致的意外”实际上是由市场监管总局最终评估确定，某某药业公司难以通过人为操纵规避承诺义务。故，北京某药业公司凭推测即主张某某药业公司可通过操纵原料药成本上升和供应不足最终实现提价目的进而损害消费者福利，缺乏依据，本院不予支持。

再次，从本案潜在进入的关注分析。其一，某某药业公司和集中后实体剥离某某药业方全部在研巴曲酶注射液业务，该承诺可消除某某药业公司与北京某药业公司在巴曲酶注射液市场上的横向重叠和潜在竞争关系。其二，某某药业公司和集中后实体对剥离买方承担原料药供应义务。价格上，以向 DSM 采购价向剥离买方供应。数量上，在剥离买方研发阶段，对于剥离买方研发所需巴曲酶原料药应当优先供应；药品获批上市后，除某某药业公司和集中后实体不可控制的因素外，不得拒绝向剥离买方供应巴曲酶原料药。该承诺能够使潜在进入者在巴曲酶原料药获取方面不劣于涉案集中未发生情况下的某某药业公司。其三，某某药业公司和集中后实体为剥离买方与 DSM 直接达成巴曲酶原料

药供应关系提供必要协助。上述承诺保障了剥离买方对巴曲酶原料药的采购来源，有利于促进研发开展。综上可知，承诺方案保障剥离买方和潜在进入者对巴曲酶原料药的采购来源。

又次，从设置备选方案分析。其一，从备选方案的设置目的看，备选方案不一定实际触发，但可起到督促某某药业公司尽快完成剥离、解除独家，从而解决潜在竞争损害的作用，有利于恢复中国境内各方向 DSM 采购的开放性，减少中间环节。其二，从实施备选方案的效果看，备选方案要求若未能实施首选方案，完成关键岗位人员变更后巴曲酶注射液下调价格将不少于当前价格的 50%。首选方案是通过促进巴曲酶注射液仿制药上市，刺激市场竞争，降低巴曲酶注射液价格以增加消费者福利。相较于首选方案的较为迂回的竞争性降价，备选方案可以直接实现大幅降价，从消费者支付价格看，比首选方案更加有效。备选方案要求集中后实体采用接近竞争性市场的经营者提供药品的价格，有利于保护消费者福利，能够解决可能的竞争损害。北京某药业公司关于备选方案不当给予了某某药业公司以独占市场的机会，可能对巴曲酶注射液的产量、质量和供给产生负面影响的主张缺乏事实依据，本院不予支持。

综上可知，承诺方案能够消除某某药业公司实施原料封锁的能力，将消除双重加价的效率提升传递到消费者，保障剥离方和潜在进入者对巴曲酶原料药的采购来源，且采用比首选方案更加严格的备选方案，具有有效性。

（二）附加限制性条件具有可行性。

部分义务的履行与案外人配合有关，为避免某某药业公司以案外人为借口拖延履行义务，市场监管总局设置了更加严格的备选方案。若未按时解除独家协议约定、未按时完成剥离或者剥离买方未按时实施研发，则适用较为严格的备选方案，可以有力督促某某药业公司和集中后实体履行解除独家协议的义务、寻找适格买方，为承诺方案履行设置“双保险”。北京某药业公司主张承诺方案采用价格监管方式和采用“尽商业上的合理努力”表述，不具有监管的可行性。对此，本院认为，一方面，从法律规定看，根据《中华人民共和国价格法》（简称价格法）和相关法律法规可知，价格监管是国家对商品和服务价格进行管理、监督和必要调控的活动，其目的是在保障市场正常运行的同时，维护国家利益、提高经济效益，保护消费者和生产经营者的合法权益。常见的价格监管措施包括政府指导价、政府定价、价格监测、价格调控和反价格欺诈等。显然，承诺方案（包括备选方案）实质上属于反垄断法意义上的与价格相关的限制性条件，其目的在于将集中带来的效率提升充分传递至消费者，而非价格法意义上的价格监管措施。另一方面，从经营者集中竞争影响评估的因素来看，商品和服务的价格直接影响消费者福利，是经营者集中竞争影响的重要评估维度，反垄断执法机构采用附加与价格相关的限制性条件作为解决竞争关注的手段之一并无不妥。《经营者集中审查规定》第三十五条第一款规定“可从价格等方面评估经营者集中对

消费者的影响”可印证该观点。此外，承诺方案中，“尽商业上的合理努力”的表述仅有两处，且均与具体行为相对应，市场监管总局可依据对具体行为是否完成的考察，结合具体事实情况判断某某药业公司是否履行了“尽商业上的合理努力”的义务，不存在北京某药业公司所主张的“不具有可监管性”。综上，北京某药业公司的相关主张，缺乏事实和法律依据，本院不予支持。某某药业公司承诺的附加限制性条件在执行过程中具备可行性。

（三）附加限制性条件具有及时性。

首先，承诺方案自公告之日起生效。生效日后，某某药业公司自身即须按时履行与 DSM 解除独家协议约定、剥离相关业务等义务。鉴于某某药业公司持有的临床试验批件有时间限制，备选方案将具体时点前未完成剥离作为触发条件之一，为剥离买方留有充足时间变更试验许可申办者、准备实施方案等前期工作。其次，某某药业公司和集中后实体承诺完成关键岗位人员变更后立即履行下调价格、保障供应义务，可避免某某药业公司长时间以无实际控制权为借口不履行保障供应、下调价格的义务，督促其于取得北京某药业公司控制权后第一时间履行义务。第三，某某药业公司和集中后实体承诺，完成关键岗位人员变更后新签署的销售订单立即下调价格，并于 3 个月内申请下调挂网价格，可避免因医保系统挂网价格调整资格介质的障碍，而导致的下调挂网价格迟延。因而，某某药业公司的附加限制性条件具备及时性。北京某药业公司主张被诉决定作出以后的一年内，某某药业公司

并没有按照承诺方案进行剥离而实际独占市场，缺乏事实依据，亦非本案审理范围。

此外，在案证据不能证明市场监管总局将仲裁结果作为被诉决定和被诉复议决定的依据，也无证据证明被诉决定仅为专家学者观点所主导。对于北京某药业公司的该诉讼主张，本院亦不予支持。

市场监管总局作出被诉决定的证据确凿，适用法律正确。被诉复议决定系在查明事实的基础上维持被诉决定，亦具有事实和法律依据，结论正确，依法应予确认。

综上所述，被诉决定及被诉复议决定均认定事实清楚，适用法律正确，程序合法。北京某药业公司的诉讼请求缺乏事实和法律依据，不予支持。依照《中华人民共和国行政诉讼法》第六十九条之规定，判决如下:

驳回原告北京某药业公司的诉讼请求。

案件受理费五十元，由原告北京某药业公司负担。（已交纳）

如不服本判决，各方当事人可在本判决书送达之日起十五日内，向本院提交上诉状，并按对方当事人人数提交副本，预交上诉案件受理费五十元，上诉于中华人民共和国最高人民法院。

审 判 长　谢甄珂

审 判 员　李迎新

审 判 员　刘欣蕾

二〇二四年十二月三十日

法官助理　雒明鑫

书 记 员　刘　颇

III. Judgment Document

Beijing Intellectual Property Court

Administrative Judgment

(2024) Jing 73 Xing Chu No. 5180

Plaintiff: Beijing X Pharmaceutical Company, Address: Haidian District, Beijing

Legal Representative: Yu X.X.

Defendant: State Administration for Market Regulation, Address: Xicheng District, Beijing

Legal Representative: Luo Wen.

Authorized Litigation Agent: Zhao X.X.

Authorized Litigation Agent: Zhan X.

Third Party: XX Pharmaceutical Company, Address: Nanjing, Jiangsu Province

Legal Representative: Ren X.X.

Authorized Litigation Agent: Huang X.

Authorized Litigation Agent: Gao X.

In the case concerning other administrative actions in anti-monopoly law between Plaintiff Beijing X Pharmaceutical Company, Defendant State Administration for Market Regulation (hereinafter referred to as the “SAMR”), and Third Party XX Pharmaceutical Company, this Court accepted the case on March 15, 2024. A collegial panel was duly formed according to law and applied the ordinary procedure. The case was heard in a closed-door hearing on September 13, 2024. Plaintiff Beijing X Pharmaceutical Company's former authorized litigation agents Yang X and Kong X.X., Defendant SAMR's authorized litigation agents Zhao X.X. and Zhan X, and Third Party XX Pharmaceutical Company's authorized litigation agents Huang X and Gao X appeared in court to participate in the proceedings. The case has now been adjudicated.

On June 29, 2022, and July 20, 2022, SAMR successively received the notification materials for the concentration of undertakings concerning XX Pharmaceutical Company's acquisition of equity of Beijing X Pharmaceutical Company (hereinafter referred to as the "Concentration in Question") submitted by Beijing X Pharmaceutical Company and XX Pharmaceutical Company. Beijing X Pharmaceutical Company and XX Pharmaceutical Company subsequently supplemented the relevant materials multiple times (hereinafter referred to as the "Notification Materials in Question"). After assessment, SAMR concluded that although the Concentration in Question did not meet the notification threshold, it may likely have the effect of eliminating or restricting competition. Therefore, SAMR formally accepted the case for review on November 23, 2022. Upon review, SAMR held that although the Concentration in Question may likely have the effect of eliminating or restricting competition in the batroxobin injection market within China, the remedy proposal submitted by XX Pharmaceutical Company on August 25, 2023 (hereinafter referred to as the "Remedy Proposal") could effectively reduce the adverse impact of the Concentration in Question on competition. This met the circumstances for conditional approval stipulated in relevant laws and regulations such as the Anti-Monopoly Law of the People's Republic of China (hereinafter referred to as the "Anti-Monopoly Law"). Consequently, SAMR made Decision No. XX (2023) (hereinafter referred to as the "Challenged Decision"), conditionally approving the Concentration in Question subject to remedies, and announced it on September 22, 2023.

Beijing X Pharmaceutical Company, dissatisfied with the Challenged Decision, applied for administrative reconsideration to SAMR within the statutory time limit. On November 21, 2023, XX Pharmaceutical Company applied to participate in the reconsideration as a Third Party, and SAMR approved the application.

On February 18, 2024, SAMR issued Administrative Reconsideration Decision No. XXX (2023) (hereinafter referred to as the "Challenged Reconsideration Decision"), deciding to uphold the Challenged Decision.

Beijing X Pharmaceutical Company, dissatisfied with the Challenged Decision and the Challenged Reconsideration Decision, filed a lawsuit with this Court requesting: 1. to revoke the Challenged Decision; 2. to revoke the Challenged Reconsideration Decision.

Facts and Grounds: 1. The Challenged Decision seriously violated the statutory hearing

procedures stipulated in the Administrative License Law of the People's Republic of China (hereinafter referred to as the "Administrative License Law"), failed to fulfill the statutory notification obligation to the interested party X Bo Co., Ltd., and severely infringed upon X Bo Co., Ltd.'s hearing rights. 2. The Challenged Decision and the Challenged Reconsideration Decision erroneously ascertained the facts. XX Pharmaceutical Company was notified by SAMR to file the notification after Beijing X Pharmaceutical Company had submitted its notification to SAMR. It did not constitute a voluntary notification. 3. The Challenged Decision and the Challenged Reconsideration Decision involved an erroneous application of law. (1) The Concentration in Question itself is a transaction that must be directly prohibited, based on the following reasons: First, the Anti-Monopoly Law mandates prohibition as the statutory and primary remedy for concentrations of undertakings that may have the effect of eliminating or restricting competition; conditional approval subject to remedies applies only under special circumstances. Second, this case involves a merger between the only two competitors in the batroxobin injection market, and the concentration would result in an exclusive monopoly, severely harming competition. Third, XX Pharmaceutical Company's method of carrying out the Concentration in Question by monopolizing the API was previously determined by SAMR to constitute an abuse of dominant market position through refusal to deal. (2) The Remedy Proposal contains major flaws and cannot effectively reduce the adverse impact on competition; therefore, it cannot serve as the basis for conditional approval. The specific reasons are as follows: First, the opinion submitted by Beijing X Pharmaceutical Company from an economic expert proves that the price reduction brought by the Remedy Proposal is far lower than that resulting from competition. It may actually increase the price of batroxobin injection, create an exclusive monopoly, and hinder competition. Second, the alternative proposal gives XX Pharmaceutical Company an opportunity to monopolize the market, potentially leading to reduced output, lower quality, and untimely supply of batroxobin injection. Furthermore, the Remedy Proposal permits XX Pharmaceutical Company to use simple price reductions as an alternative proposal to divestiture, thereby transforming the State Council's anti-monopoly law enforcement agency from a guardian of market competition into a price regulator. Third, XX Pharmaceutical Company could ultimately achieve price increases by manipulating the rising cost and insufficient supply of the API. Fourth, XX Pharmaceutical Company could take relevant measures to artificially cause batroxobin injection to be listed on the Drug Shortages List, thereby evading the 20% price commitment requirement.

Furthermore, the Remedy Proposal stipulates "unforeseeable events caused by factors beyond XX Pharmaceutical Company's control" as an exception to the breach of the remedies to "avoid Tobishi batroxobin injection being listed on the National Drug Shortages List or the Key Monitoring List for Clinically Essential and Easily Shortaged Drugs". SAMR's Penalty Decision No. X (2021) (hereinafter referred to as "Penalty Decision X") can corroborate that XX Pharmaceutical Company can "artificially" influence DSM's inventory situation and evade supervision by causing supply interruptions. Fifth, the "commercially reasonable efforts" clause in the Remedy Proposal lacks clear regulatory standards and is not amenable to supervision. Sixth, within one year after the Challenged Decision was made, XX Pharmaceutical Company did not proceed with the divestiture according to the Remedy Proposal and has effectively achieved the purpose of monopolizing the market. Additionally, the arbitration outcome and expert consultation opinions should not affect the review of this case.

SAMR contended that Beijing X Pharmaceutical Company was not a qualified plaintiff in this case. Furthermore, the Challenged Decision and the Challenged Reconsideration Decision had clearly ascertained the facts, correctly applied laws and regulations, and followed lawful review procedures. The litigation grounds raised by Beijing X Pharmaceutical Company were unfounded. Therefore, it requested that the Court dismiss Beijing X Pharmaceutical Company's lawsuit or reject all its claims in accordance with the law.

XX Pharmaceutical Company stated that the Challenged Decision and the Challenged Reconsideration Decision issued by SAMR were based on conclusive evidence, correctly applied the law, and complied with statutory procedures. Beijing X Pharmaceutical Company's claims lacked factual and legal basis. Therefore, the Court should dismiss Beijing X Pharmaceutical Company's lawsuit or reject all its claims.

In this litigation, Beijing X Pharmaceutical Company, SAMR, and XX Pharmaceutical Company, regarding the grounds of the lawsuit, arguments in defense, and statements, submitted evidence in accordance with the law. This Court organized the parties to conduct the exchange and cross-examination of evidence.

Upon trial, this Court ascertains the following facts:

I. Facts Relating to the Acquisition of Equity of Beijing X Pharmaceutical Company

Beijing X Pharmaceutical Company was established in Beijing in 1993. Its equity holder, X Bo Co., Ltd., was established in Hong Kong, China, and its ultimate controller is a natural person. Beijing X Pharmaceutical Company engages in the production and sale of batroxobin injection and is currently the only enterprise in China possessing the production qualification and capacity for batroxobin injection.

XX Pharmaceutical Company was established in Nanjing, Jiangsu Province in 1998. Its parent company, XX Pharmaceutical Group Co., Ltd. (hereinafter referred to as "XX Pharmaceutical Group"), was established in Hong Kong, China, and listed on the Hong Kong Stock Exchange. Its ultimate controller is a natural person. XX Pharmaceutical Company and its affiliates (hereinafter collectively referred to as "XX Pharmaceutical Party") are primarily engaged in the production and sale of pharmaceuticals. XX Pharmaceutical Party is researching and developing batroxobin injection.

In June 2016, Da X Lin Company, whose legal representative was Zhou X.X., was authorized by Swiss DSM Nutritional Products Ltd Branch Pentapharm (the company and its affiliates hereinafter collectively referred to as DSM), the sole global supplier of batroxobin concentrate active pharmaceutical ingredient (hereinafter referred to as "batroxobin API"), to obtain the exclusive distribution right for batroxobin API within China. In December of the same year, the legal representative of Beijing X Pharmaceutical Company was changed to Zhou X.X.

On July 21, 2017, XX Pharmaceutical Party signed an Equity Transfer Agreement (hereinafter referred to as the "Concentration Agreement") with X Bo Co., Ltd., intending to acquire 100% equity in Beijing X Pharmaceutical Company.

On March 27, 2019, Jiangxi Puyuan Health Industry Co., Ltd. (hereinafter referred to as "Puyuan Company") and Zhou X.X. signed an agreement regarding the acquisition of 100% equity in Beijing X Pharmaceutical Company and X Bo Co., Ltd. They subsequently signed a Control Handover Confirmation Slip on April 22, 2019. On May 15, 2019, the legal representative and board members of Beijing X Pharmaceutical Company were changed pursuant to the Equity Acquisition Agreement.

On April 29, 2019, XX Pharmaceutical Party signed a Cooperation and Supply Agreement with DSM, becoming the only company authorized to sell batroxobin API in China's domestic

market.

On July 25, 2019, XX Pharmaceutical Party, naming X Bo Co., Ltd. et al. as respondents, requested that X Bo Co., Ltd. et al. pay liquidated damages of RMB 50 million yuan based on X Bo Co., Ltd.'s breach of the Concentration Agreement. On March 27, 2020, the Shanghai International Economic and Trade Arbitration Commission rendered an arbitral award upholding XX Pharmaceutical Party's claim that X Bo Co., Ltd. pay liquidated damages of RMB 50 million yuan.

In September 2020, Beijing X Pharmaceutical Company reported to SAMR alleging that XX Pharmaceutical Party's refusal to supply batroxobin API to Beijing X Pharmaceutical Company constituted abuse of a dominant market position.

SAMR issued Penalty Decision No. 1 on January 22, 2021, determining that the actions of XX Pharmaceutical Party constituted an abuse of dominant market position through refusal to deal. SAMR ordered XX Pharmaceutical Party to cease the illegal acts and imposed a fine equivalent to 2% of its annual sales revenue of RMB 5.0367 billion yuan for the year 2019, totaling RMB 100.7 million yuan.

On April 7, 2021, XX Pharmaceutical Party once again filed an arbitration application against X Bo Co., Ltd. and others as respondents, requesting that X Bo Co., Ltd. continue to perform the Concentration Agreement by transferring its 100% equity in Beijing X Pharmaceutical Company to XX Pharmaceutical Party. On January 18, 2022, the Shanghai International Economic and Trade Arbitration Commission issued Award No. 0195 [2022] (hereinafter referred to as the "No. 195 Award"), which determined that the Concentration Agreement signed between XX Pharmaceutical Party and X Bo Co., Ltd. in 2017 was legally valid and binding upon both parties, who should perform their obligations according to the contract. The Award thus granted XX Pharmaceutical Party's request for the equity transfer.

X Bo Co., Ltd., dissatisfied with the No. 195 Award, applied to the Second Intermediate People's Court of Shanghai Municipality to set aside the arbitral award. In August 2022, the Second Intermediate People's Court of Shanghai Municipality ruled to dismiss X Bo Co., Ltd.'s application. Later, X Bo Co., Ltd. applied to the First Intermediate People's Court of Beijing Municipality for non-enforcement of the arbitral award. In August 2023, the First Intermediate People's Court of Beijing Municipality ruled to dismiss X Bo Co., Ltd.'s application for non-

enforcement of the arbitral award.

Puyuan Company, dissatisfied with the No. 195 Award, applied to the First Intermediate People's Court of Beijing Municipality for non-enforcement and suspension of enforcement of the arbitral award. In February and April 2023, the First Intermediate People's Court of Beijing Municipality respectively ruled to dismiss Puyuan Company's applications for non-enforcement and suspension of enforcement of the arbitral award. Dissatisfied with the above rulings, Puyuan Company applied to the High People's Court of Beijing Municipality for reconsideration. In June 2023, the High People's Court of Beijing Municipality ruled to dismiss Puyuan Company's application for reconsideration, upholding the above rulings made by the First Intermediate People's Court of Beijing Municipality.

On April 7, 2024, the First Intermediate People's Court of Beijing Municipality issued the Enforcement Ruling (2023) Jing 01 Zhi Hui No. 256, ruling to change the registration of 100% equity in Beijing X Pharmaceutical Company to XX Pharmaceutical Company's name.

On April 9, 2024, pursuant to the Company Law of the People's Republic of China and other relevant laws and regulations as well as the company's articles of association, XX Pharmaceutical Company adopted a shareholder resolution to remove Xiong Guoqing, Cheng Jun, Yu Shulin, Xiong Guohuang, Wang Yankun, and Chen Yanyi from their positions as directors and supervisors. Simultaneously, it appointed Yu Qingzhu, Yang Yang, Tang Tiangui, Mao Tingting, Wang Dandan, and Hou Zhiwei as directors and supervisors of Beijing X Pharmaceutical Company, with Yu Qingzhu serving as Chairman of the Board and Legal Representative.

X Bo Co., Ltd., on the grounds that the performance period of the No. 195 Award was unclear and that XX Pharmaceutical Party had not paid the equity transfer price, applied to the First Intermediate People's Court of Beijing Municipality for the execution restitution of the equity in Beijing X Pharmaceutical Company to X Bo Co., Ltd.'s name. On April 25, 2024, the First Intermediate People's Court of Beijing Municipality ruled to dismiss X Bo Co., Ltd.'s application. Dissatisfied, X Bo Co., Ltd. applied to the High People's Court of Beijing Municipality for reconsideration. On June 18, 2024, the High People's Court of Beijing Municipality ruled to dismiss X Bo Co., Ltd.'s application for reconsideration.

On July 10, 2024, the Primary People's Court of Zhanggong District of Ganzhou City,

Jiangxi Province, issued a pre-litigation behavior preservation ruling based on the application of Jiangxi Puqing Pharmaceutical Co., Ltd. The ruling prohibited Beijing X Pharmaceutical Company from processing industrial and commercial changes or filing registrations for its legal representative.

On December 9, 2024, the Supreme People's Court of the People's Republic of China issued the Civil Ruling (2024) Zui Gao Fa Zhi Min Zhong No. 702 in the second instance of the refusal-to-deal dispute between appellant Beijing X Pharmaceutical Company and appellants XX Pharmaceutical Group Co., Ltd. and Jiangsu XX Pharmaceutical Company. The ruling stated: "The present dispute now actually arises between Beijing X Pharmaceutical Company and its sole shareholder XX Pharmaceutical Company, as well as XX Pharmaceutical Group Co., Ltd. and Jiangsu XX Pharmaceutical Company. The above entities are all affiliated companies and were aware of the fact that XX Pharmaceutical Company adopted a shareholder resolution to change the legal representative of Beijing X Pharmaceutical Company to Yu Qingzhu. None of them are 'bona fide counterparties' unaware of this fact. Therefore, in this case, the shareholder resolution made by XX Pharmaceutical Company as the sole shareholder of Beijing X Pharmaceutical Company shall prevail, confirming that the legal representative of Beijing X Pharmaceutical Company has been changed to Yu Qingzhu. Yu Qingzhu's act of withdrawing the appeal on behalf of Beijing X Pharmaceutical Company shall be deemed the genuine expression of the company's intent. The request by Beijing X Pharmaceutical Company to withdraw its appeal during the trial of this case does not violate legal provisions. The requests by XX Pharmaceutical Group Co., Ltd. and Jiangsu XX Pharmaceutical Company to withdraw their appeals during the trial of this case likewise do not violate legal provisions and are hereby granted."

After the above ruling was issued, Yu Qingzhu, the legal representative of Beijing X Pharmaceutical Company, stated that no further court hearing was needed and no written opinion would be submitted, requesting the Court to rule according to law.

II. Relevant Facts Concerning the Notification of Concentration in Question

On June 29 and July 20, 2022, Beijing X Pharmaceutical Company and XX Pharmaceutical Company respectively submitted their concentration notification materials to SAMR.

On November 23, 2022, SAMR lawfully issued a Notice of Case Acceptance regarding the notification of Concentration in Question and served it to XX Pharmaceutical Company and Beijing X Pharmaceutical Company the following day.

On December 21, 2022, SAMR lawfully issued a Decision on Proceeding to Further Review and served it to XX Pharmaceutical Company and Beijing X Pharmaceutical Company on the same day.

On March 17, 2023, SAMR notified XX Pharmaceutical Company and Beijing X Pharmaceutical Company of competition concerns that the Concentration in Question may likely have the effect of eliminating or restricting competition in China's batroxobin injection market. SAMR required the notifying parties to submit a Remedy Proposal and informed them that written defenses could be submitted within 10 working days. XX Pharmaceutical Company indicated it would promptly submit the Remedy Proposal, while Beijing X Pharmaceutical Company acknowledged the competition concerns and continued to submit opinions.

On March 19, 2023, upon consent from XX Pharmaceutical Company and Beijing X Pharmaceutical Company, SAMR decided to extend the further review period. The review period for the Concentration in Question was extended to May 17, 2023. This decision was served to XX Pharmaceutical Company and Beijing X Pharmaceutical Company on March 19, 2023.

On April 25, 2023, SAMR made a decision to suspend the calculation of the review period. The calculation of the review period resumed on September 21, 2023. The relevant decisions were served to XX Pharmaceutical Company and Beijing X Pharmaceutical Company on April 25, 2023, and September 21, 2023, respectively.

During its review of the Concentration in Question, SAMR solicited written comments from relevant entities, including competent industry authorities. Neither the competent industry authorities, industry associations, nor other relevant entities raised objections to the Concentration in Question. Some entities recommended requiring the enterprises to commit to maintaining relatively stable end-user prices for batroxobin injection products post-acquisition. Additionally, they suggested that if batroxobin products from other enterprises are approved afterward, XX Pharmaceutical Company should provide fair treatment to all

enterprises when supplying API.

During its investigation, SAMR surveyed frontline units including hospitals in Beijing. Hospitals generally reported that batroxobin injection plays a difficult-to-substitute role in treating sudden deafness with full-frequency hearing loss, and they had not used defibrase injections or similar alternatives. The Center for Drug Evaluation of the National Medical Products Administration (NMPA) explained the differences between approved drug indications and clinical applications, and described the challenges in developing batroxobin injection, noting the objective reality that snake venom-derived drugs had not been approved for many years.

SAMR engaged an independent third-party institution to conduct an economic analysis of the Concentration in Question. The economic analysis found that the current vertically double monopolistic market structure was highly inefficient. If XX Pharmaceutical Company were to acquire Beijing X Pharmaceutical Company, the batroxobin API would transition to internal supply, eliminating the markup when XX Pharmaceutical Company supplies Beijing X Pharmaceutical Company. This could create room for reducing price markups and improving market supply efficiency. However, the vertically integrated market efficiency formed post-acquisition would remain relatively low, and whether the improved efficiency could be passed on to consumers remained uncertain. The third-party institution also provided recommendations regarding remedies.

On April 13, 2023, SAMR organized an expert consultation meeting to specifically discuss case resolution approaches. Experts unanimously agreed that this case involved two distinct acts separate from the previous abuse of market dominance case, and recommended concluding the case by imposing remedies.

Beginning in April 2023, XX Pharmaceutical Company submitted multiple versions of Remedy Proposals and explanatory letters.

On July 10, 2023, SAMR solicited opinions from relevant entities—including competent authorities, industry associations, DSM, and Beijing X Pharmaceutical Company—regarding the Remedy Proposal submitted by XX Pharmaceutical Company on July 10, 2023. Some responses suggested that the enterprise should ensure the supply of batroxobin injection in the clinically common specification (0.5ml:5BU) during subsequent production. Apart from

Beijing X Pharmaceutical Company, which recommended prohibiting the proposal, no other units raised objections to the Remedy Proposal.

Subsequently, XX Pharmaceutical Company further revised the Remedy Proposal, and submitted the final version on August 25, 2023. XX Pharmaceutical Company and the post-concentration entity committed to the following:

First, terminate the exclusive supply agreement between XX Pharmaceutical Company and DSM for batroxobin API within China. After the termination of exclusive agreement, XX Pharmaceutical Company shall not enter into any exclusive or sole supply agreement with DSM for batroxobin API in China. Except for supplying batroxobin API to meet XX Pharmaceutical Company's production needs for Beijing X Pharmaceutical Company's batroxobin injection, ensuring reasonable API requirements for Beijing X Pharmaceutical Company's production before the completion of key personnel changes, and providing transitional services to the divestiture buyer, XX Pharmaceutical Company shall not retain resale rights for batroxobin API. Simultaneously, XX Pharmaceutical Company shall not restrict Beijing X Pharmaceutical Company (prior to the completion of key personnel changes) or the divestiture buyer from directly procuring batroxobin API from DSM or other parties.

Second, divest XX Pharmaceutical Company's ongoing batroxobin injection R&D project within the timeframe stipulated in the Provisions on the Review of Concentration of Undertakings. Assume the obligation to supply batroxobin API to the divestiture buyer, prioritizing the supply of batroxobin API required for the divestiture buyer to continue the research and development of Simcere's self-developed batroxobin injection. If the divestiture buyer obtains approval for marketing Simcere's self-developed batroxobin injection after continued R&D, XX Pharmaceutical Company shall not refuse to supply batroxobin API to the divestiture buyer, except due to factors beyond Simcere's control. XX Pharmaceutical Company should exert commercially reasonable efforts, with the cooperation of the divestiture buyer, to assist the divestiture buyer in completing the sponsorship transfer for the clinical trial authorization of Simcere's self-developed batroxobin injection on the clinical trial information registration platform. XX Pharmaceutical Company should exert commercially reasonable efforts to provide necessary assistance to the divestiture buyer in establishing a direct supply relationship with DSM.

Third, reduce the end-user price of batroxobin injection in clinically common specifications by no less than 20% of the current listed price starting from the date of completion of key personnel changes. The listed price for Beijing X Pharmaceutical Company's batroxobin injection may only be reasonably increased if production costs rise due to exchange rate fluctuations or raw material price changes, and any increase shall not exceed the actual rise in production costs.

Fourth, ensure the supply of batroxobin injection in clinically common specifications to meet clinical demand starting from the date of completion of key personnel changes. Prevent Beijing X Pharmaceutical Company's batroxobin injection from being listed in the National Drug Shortages List or the Key Monitoring List for Clinically Essential and Easily Shortaged Drugs, except when caused by factors beyond XX Pharmaceutical Company's control.

Fifth, if the agreement is not terminated on schedule, the divestiture is not completed on time, or the divestiture buyer fails to implement R&D as scheduled, the end-user price of batroxobin injection in clinically common specifications shall be reduced by no less than 50% of the current listed price after the concentration is implemented. XX Pharmaceutical Company may only reasonably increase the listed price for Beijing X Pharmaceutical Company's batroxobin injection due to increased production costs caused by exchange rate fluctuations or raw material price changes, and any increase shall not exceed the actual rise in production costs.

The remedies are legally binding on XX Pharmaceutical Company and the post-concentration entity, and their supervision and execution shall be handled in accordance with the announcement.

The behavioral remedies shall remain in effect for 6 years from the effective date. SAMR will decide whether to remove these remedies upon application and based on market competition conditions. Unless SAMR approves their removal, XX Pharmaceutical Company and the post-concentration entity shall continue to comply with these remedies.

SAMR has the authority to supervise and inspect the fulfillment of the above obligations by XX Pharmaceutical Company and the post-concentration entity, either through a supervisory trustee or directly. Should XX Pharmaceutical Company and the post-concentration entity fail to fulfill the above obligations, SAMR may take action in accordance

with relevant provisions of the Anti-Monopoly Law.

III. Content of the Challenged Decision and Challenged Reconsideration Decision

On September 22, 2023, SAMR issued the Challenged Decision and publicly announced it on the same day. Subsequently, it was served to XX Pharmaceutical Company and Beijing X Pharmaceutical Company.

Content of the Challenged Decision:

XX Pharmaceutical Company engages in the sale of batroxobin API, while Beijing X Pharmaceutical Company engages in the production and sale of batroxobin injection. The two companies maintain a vertical relationship. Simultaneously, XX Pharmaceutical Company is developing batroxobin injection, creating a horizontal overlap with Beijing X Pharmaceutical Company. The Concentration in Question involves China's batroxobin API sales market and batroxobin injection market, which may likely have the effect of eliminating or restricting competition in China's batroxobin injection market. On one hand, the concentration may eliminate potential entrants to China's batroxobin injection market, thereby consolidating Beijing X Pharmaceutical Company's dominant position in this market and generating effects that eliminate or restrict competition. On the other hand, the post-concentration entity may engage in input foreclosure, creating effects that eliminate or restrict competition in China's batroxobin injection market. Batroxobin injection—a fibrinogen-reducing drug—is difficult to substitute with other medications in treating sudden deafness with full-frequency hearing loss. During the review process, SAMR informed the notifying party, XX Pharmaceutical Company, of its preliminary view that the concentration may likely have the effect of eliminating or restricting competition. Multiple rounds of discussions were held with the notifying parties regarding measures to mitigate adverse effects on competition. After evaluating the Remedy Proposal submitted by XX Pharmaceutical Company—with emphasis on the effectiveness, feasibility, and timeliness of the remedies—SAMR determined that the Remedy Proposal submitted on August 25, 2023, could mitigate the adverse effects of this concentration on competition and lower patient medication costs.

In view of the effect of eliminating or restricting competition this concentration may likely have on China's batroxobin injection market, SAMR decided to approve the concentration subject to remedies.

The Challenged Decision takes effect from the date of its announcement. As an annex to the announcement of the Challenged Decision, the Remedy Proposal submitted by XX Pharmaceutical Company on August 25, 2023, and publicly released by SAMR, takes effect on the same date as the Challenged Decision.

On November 13, 2023, the legal department of SAMR received and accepted the administrative reconsideration application filed by Beijing X Pharmaceutical Company challenging the Challenged Decision.

On February 18, 2024, SAMR issued the Challenged Reconsideration Decision, affirming that the Challenged Decision had clear factual findings, correctly applies law, and complied with statutory procedures. The Decision was therefore upheld. On February 22, 2024, SAMR served the Challenged Reconsideration Decision to Beijing X Pharmaceutical Company.

The above facts are substantiated by evidence on record, including: notification materials, supplementary materials, Penalty Decision No. X, Remedy Proposals and explanatory letters, the Challenged Decision, the Challenged Reconsideration Decision, research reports, cooperation and supply agreements, communication records, clinical trial approvals, prospectuses, batroxobin injection instructions, statements of explanation, economic assessment reports, expert opinions and supplementary opinions, civil judgments, arbitral awards, emails and email records, payment vouchers, invoices, notices, decisions, and the parties' statements.

This Court holds: Based on the claims, defenses, and statements of all parties, this case involves the following five controversial issues: 1. Whether Beijing X Pharmaceutical Company qualifies as a proper plaintiff in this case; 2. Whether the issuance of the Challenged Decision involved procedural violations; 3. Whether the Challenged Decision contains factual errors; 4. Whether SAMR's approval of the Concentration in Question subject to remedies was lawful; 5. Whether SAMR's adoption of XX Pharmaceutical Company's Remedy Proposal as conditions for approving the concentration was lawful.

I. Regarding Whether Beijing X Pharmaceutical Company Qualifies as a Proper Plaintiff in This Case

Article 25(1) of the Administrative Procedure Law of the People's Republic of China

(hereinafter referred to as the "Administrative Procedure Law") stipulates that "An administrative counterpart or any citizen, legal person or other organization who or which has interests in a specific administrative act have the right to initiate an action". Article 69(1)(8) of the Interpretations of the Supreme People's Court on the Application of the Administrative Procedure Law of the People's Republic of China provides that if any of the following circumstances exists after a case has been filed, the Court shall rule to dismiss the lawsuit: (8) where the administrative act has no material effect on the party's legitimate rights and interests. The specific administrative act conducted by SAMR concerning the notification of a concentration of undertakings is administrative license in nature. Where SAMR issues a non-prohibition decision regarding a concentration notification, such specific administrative act neither alters nor increases the rights and obligations of the notifying parties arising from the concentration agreement. Consequently, it does not affect their legitimate rights and interests, and none of the notifying parties possesses a legal interest sufficient to initiate administrative litigation. However, where SAMR issues a prohibition decision or a conditional approval decision, such specific administrative act negates the rights and obligations of the notifying parties arising from the concentration agreement or imposes statutory obligations on the post-concentration notifying party. This affects the legitimate rights and interests of the relevant notifying party, who therefore possesses a legal interest sufficient to initiate administrative litigation.

Specifically regarding this case, the Challenged Decision is a conditional approval decision. The attached remedies were proposed by one notifying party, XX Pharmaceutical Company, rather than the other notifying party, Beijing X Pharmaceutical Company. Therefore, the remedies attached to the Challenged Decision will de facto impose statutory obligations on Beijing X Pharmaceutical Company post-concentration, materially affecting its legitimate rights and interests. Consequently, Beijing X Pharmaceutical Company possesses a legal interest sufficient to initiate this administrative litigation and qualifies as a proper plaintiff in this case. The relevant claims put forth by SAMR and XX Pharmaceutical Company lack legal basis, and are not sustained by this Court.

II. Regarding Whether the Issuance of the Challenged Decision Involved Procedural Violations

Article 47 of the Administrative License Law stipulates, where an administrative license

is of direct significance to the interests of the applicant or others, before the administrative organ makes a decision about the administrative license, it shall inform the applicant or the interested party of the right to request for a hearing. Where the applicant or interested party applies for a hearing within 5 days from the day when it is informed of such right, the administrative organ shall organize a hearing within 20 days.

In this case, X Bo Co., Ltd.—which Beijing X Pharmaceutical Company asserts should have been granted hearing rights—does not fall within the category of parties required to be informed under the aforementioned legal provision.

On one hand, analyzing whether the Challenged Decision involves the relationship between X Bo Co., Ltd. and XX Pharmaceutical Company: The contractual rights and obligations between XX Pharmaceutical Company and X Bo Co., Ltd. constitute a civil legal relationship. The validity and enforcement of relevant contracts are governed by arbitral awards and court rulings. The Challenged Decision merely took the above circumstances into account as factual considerations and did not create or alter the contractual rights and obligations between the two parties. Therefore, the Challenged Decision does not involve the interests between XX Pharmaceutical Company and X Bo Co., Ltd., let alone any major interests between them.

On the other hand, analyzing the relevance of X Bo Co., Ltd. to the Challenged Decision, the Challenged Decision only imposes obligations on XX Pharmaceutical Company and Beijing X Pharmaceutical Company (which post-concentration will be controlled by XX Pharmaceutical Company). These obligations do not directly involve the relationship between X Bo Co., Ltd. and either XX Pharmaceutical Company or Beijing X Pharmaceutical Company. It must be emphasized that X Bo Co., Ltd.'s obligation to transfer its equity in Beijing X Pharmaceutical Company to XX Pharmaceutical Company does not arise from obligations imposed or effects caused by the Challenged Decision. Rather, it stems from the concentration agreement voluntarily reached between X Bo Co., Ltd. and XX Pharmaceutical Company based on the autonomy of will. Therefore, the impact on X Bo Co., Ltd. alleged by Beijing X Pharmaceutical Company lacks direct relevance to the Challenged Decision.

Furthermore, Beijing X Pharmaceutical Company's claim that "XX Pharmaceutical Company forcibly completed the industrial and commercial registration change for 100%

equity of Beijing X Pharmaceutical Company without paying any consideration" involves a civil legal relationship between the parties. This matter should be addressed by a People's Court or an arbitral institution. It is unrelated to the Challenged Decision, which constitutes administrative license in nature, and also unrelated to the administrative legal relationship at issue in this case. Moreover, it fails to demonstrate that X Bo Co., Ltd. should have been granted hearing rights regarding the issuance of the Challenged Decision. Therefore, this Court declines to comment on Beijing X Pharmaceutical Company's related claims.

SAMR fulfilled statutory procedures—including notification and service—within the legally prescribed time limits, thereby safeguarding Beijing X Pharmaceutical Company's procedural rights. The administrative process for issuing the Challenged Decision was lawful and proper. Beijing X Pharmaceutical Company's claim that the issuance of the Challenged Decision violated procedural law lacks factual and legal basis, and is not sustained by this Court.

III. Regarding Whether the Challenged Decision Contains Factual Errors

The acquisition of equity of Beijing X Pharmaceutical Company by XX Pharmaceutical Company constituted a voluntary notification with SAMR prior to the implementation of the Concentration in Question. This was permissible under relevant regulations since Beijing X Pharmaceutical Company failed to meet the turnover threshold, and SAMR had not issued a written formal requirement for notification. The Challenged Decision's determination on this matter was without impropriety. Beijing X Pharmaceutical Company's assertion that the Challenged Decision contains factual errors is unfounded, and is not sustained by this Court.

IV. Regarding Whether SAMR's Approval of the Concentration in Question Subject to Remedies Was Lawful

SAMR has the authority to approve the Concentration in Question subject to remedies. Article 26 (1) of the Anti-Monopoly Law stipulates, where a concentration of undertakings reaches the threshold level as set by the State Council, undertakings shall notify in advance to the anti-monopoly enforcement agency under the State Council. They shall not implement the concentration in the absence of such notification. Where a concentration of undertakings does not reach the threshold level prescribed by the State Council, but there is evidence that the concentration may have or may likely have an effect of eliminating or restricting competition,

the anti-monopoly enforcement agency under the State Council may also require notification by undertakings. Meanwhile, Article 16 of the Interim Provisions on the Review of Concentration of Undertakings provides that, where a concentration of undertakings does not reach the threshold level and the undertakings participating in the concentration voluntarily file a notification, SAMR shall, after receiving the notification documents and materials and when it deems it necessary to initiate a case after review, initiate a case for review and make a decision in accordance with the Anti-Monopoly Law.

The Interim Provisions on the Review of Concentration of Undertakings are formulated in accordance with the Anti-Monopoly Law, and Article 16 stipulates that reviews shall be conducted "in accordance with the Anti-Monopoly Law". Therefore, when a concentration of undertakings does not reach the threshold level, the review standards for "voluntary notification" should be the same as those for "required notification" explicitly provided under the Anti-Monopoly Law.

Article 34 of the Anti-Monopoly Law stipulates that, where a concentration of undertakings may have or may likely have an effect of eliminating or restricting competition, the anti-monopoly enforcement agency of the State Council shall make a decision to prohibit the concentration. If the undertakings, however, can prove that the positive impact of the concentration on competition conspicuously outweighs the adverse impact, or that the concentration is in line with the public interests, the anti-monopoly enforcement agency under the State Council may decide not to prohibit the concentration. Article 35 of the Anti-Monopoly Law stipulates, where the anti-monopoly enforcement agency under the State Council does not prohibit the concentration of undertakings, it may decide to impose remedies for lessening the negative impact exerted by such concentration on competition.

In this case, the Concentration in Question involves XX Pharmaceutical Company's acquisition of 100% equity of Beijing X Pharmaceutical Company, constituting a concentration of undertakings as defined by the Anti-Monopoly Law. Although the Concentration in Question does not meet the threshold level for notifying concentrations of undertakings, pursuant to Article 26 of the Anti-Monopoly Law and Article 16 of the Interim Provisions on the Review of Concentration of Undertakings, SAMR has the authority to conduct an anti-monopoly review of the Concentration in Question. In accordance with relevant provisions of the Anti-Monopoly Law and the Provisions on the Review of

Concentration of Undertakings, for concentrations of undertakings that may have or may likely have the effect of eliminating or restricting competition, SAMR may render different types of decisions – such as a decision not to prohibit, conditional approval, or prohibition – based on the specific circumstances of the case, and thus has the authority to issue a decision approving the Concentration in Question subject to remedies.

Based on the facts on record, XX Pharmaceutical Party, through its Cooperation and Supply Agreement with DSM, has obtained exclusive access to all batroxobin API sources in China, thereby controlling the batroxobin API sales market in China. The sole downstream application of this API in China is batroxobin injection. Beijing X Pharmaceutical Company is currently the only batroxobin injection manufacturer in China, while XX Pharmaceutical Party is developing its own batroxobin injection. Consequently, XX Pharmaceutical Company and Beijing X Pharmaceutical Company exhibit both horizontal overlap in the batroxobin injection market and a vertical relationship in the batroxobin API sales market. Given that batroxobin injection is a fibrinogen-reducing drug and is difficult to substitute with other medications in the treatment of sudden deafness with full-frequency hearing loss, the Concentration in Question involves the batroxobin API sales market and the batroxobin injection market in China, and may likely have the effect of eliminating or restricting competition in China's batroxobin injection market. On one hand, the concentration may eliminate potential entrants to China's batroxobin injection market, thereby consolidating Beijing X Pharmaceutical Company's dominant position in this market and generating effects that eliminate or restrict competition. On the other hand, the post-concentration entity may engage in input foreclosure, creating effects that eliminate or restrict competition in China's batroxobin injection market.

Beijing X Pharmaceutical Company, based on its understanding that prohibition is the "statutory and primary remedy" for concentrations that may have or may likely have the effect of eliminating or restricting competition, and considering the specific circumstances of the Concentration in Question, argued that "this Concentration itself is a transaction that must be directly prohibited". SAMR, however, maintained that prohibiting a concentration is not the primary remedy for concentrations that may have or may likely have the effect of eliminating or restricting competition; rather, conditional approval may be granted if the undertakings can propose an effective Remedy Proposal. SAMR further held that the Concentration in Question

in this case did not fall into the category of transactions that must be prohibited. Regarding this, this Court holds that:

Firstly, from the perspective of legal provisions, while the Anti-Monopoly Law establishes the review system for concentrations of undertakings, Article 6 of the Anti-Monopoly Law stipulates that undertakings may lawfully implement concentrations, expand their scale of operations, and enhance their market competitiveness through fair competition and voluntary combination. This demonstrates that the Anti-Monopoly Law explicitly establishes the principle of "exceptional intervention" regarding concentrations of undertakings. Meanwhile, Articles 34 and 35 of the Anti-Monopoly Law do not designate prohibition as the statutory and primary remedy. Instead, it is stipulated that "Where the anti-monopoly enforcement agency under the State Council does not prohibit the concentration of undertakings, it may decide to impose remedies for lessening the negative impact exerted by such concentration on competition". The specific provisions within Chapter IV of the Anti-Monopoly Law should be understood in conjunction with the principle of "exceptional intervention" under Article 6, and should not be interpreted mechanically in isolation. Article 39 (1) and (2) of the Provisions on the Review of Concentration of Undertakings further stipulate: "To reduce the effect of eliminating or restricting competition that the concentration may have or may likely have, the undertakings participating in the concentration may submit to SAMR a Remedy Proposal. SAMR shall assess the effectiveness, feasibility, and timeliness of the Remedy Proposal and promptly inform the notifying party of the assessment results". This indicates that for concentrations of undertakings that may have or may likely have the effect of eliminating or restricting competition, SAMR is not required to directly prohibit the concentration as a matter of course. The participating undertakings may propose a Remedy Proposal, and SAMR shall assess such proposal. Only if the assessment concludes that the Remedy Proposal cannot effectively reduce the adverse effects of the concentration on competition should SAMR make a decision to prohibit the concentration. Beijing X Pharmaceutical Company's assertion that "the Anti-Monopoly Law mandates prohibition as the statutory and primary remedy for concentrations of undertakings that may have the effect of eliminating or restricting competition; conditional approval subject to remedies applies only under special circumstances" misinterprets the Anti-Monopoly Law. Its relevant litigation claims lack legal basis, and are not sustained by this Court.

Secondly, from the perspective of the purpose of anti-monopoly review of concentrations of undertakings, "the concentration of undertakings that may have or may likely have the effect of eliminating or restricting competition" refers to "competition concerns arising from the concentration itself." The primary objective of enforcement in the review of concentrations of undertakings is to address competition concerns arising from the concentration, instead of those that existed prior to the concentration. Specifically in this case, the current competitive conditions in the batroxobin injection market are not the focus of the concentration review. Even assuming arguendo the position of Beijing X Pharmaceutical Company, in terms of the number of competitors in the competitive structure, both before and after the concentration, the relevant market contained one incumbent competitor and one potential entrant. That is, the number of market competitors would be the same under both scenarios: prohibiting the concentration or approving the concentration subject to remedies. Furthermore, as previously stated, if the Remedy Proposal can address the competition concerns arising from the Concentration in Question itself and effectively reduce the potential adverse effects of the concentration on competition, then SAMR could issue a decision approving the concentration subject to remedies.

Finally, SAMR's Penalty Decision No. 1 regarding XX Pharmaceutical Company was an administrative penalty against XX Pharmaceutical Company's refusal to deal in China's batroxobin API sales market. In contrast, the Challenged Decision is an administrative license issued after reviewing whether XX Pharmaceutical Company's acquisition of equity in Beijing X Pharmaceutical Company may have the effect of eliminating or restricting competition. The two are different in nature. Moreover, the Concentration Agreement underlying the Concentration in Question—signed in 2017 between XX Pharmaceutical Party and X Bo Co., Ltd.—was not entered into under duress arising from abuse of a dominant market position. The validity of the Concentration Agreement has been confirmed by arbitration awards and judicial decisions from the relevant arbitration institution and People's Court. This further demonstrates that Beijing X Pharmaceutical Company's assertion that "the execution of the Concentration Agreement constituted a specific manifestation or direct consequence of the aforementioned abuse of a dominant market position" cannot be substantiated. It must be emphasized that the review of a concentration of undertakings is an ex-ante examination and determination of whether a specific transaction may have or may likely have the effect of

eliminating or restricting competition. Whether the transaction is ultimately implemented is irrelevant to the decision of the concentration review. In the review of concentrations of undertakings, SAMR has neither the obligation nor the need to conduct a substantive review of the validity of the Concentration Agreement. If the parties to the transaction dispute the validity of the Concentration Agreement, it should be confirmed by an arbitration institution or a People's Court in accordance with legal provisions and the terms of the agreement. In summary, whether XX Pharmaceutical Company is found to have engaged in abuse of a dominant market position through refusal to deal is unrelated to the review of the Concentration in Question. Moreover, this cannot prove that the Concentration in Question must therefore be directly prohibited.

In conclusion, SAMR's approval of the Concentration in Question subject to remedies was lawful. All relevant litigation claims put forth by Beijing X Pharmaceutical Company lack factual and legal basis, and are not sustained by this Court.

V. Regarding Whether SAMR's Adoption of XX Pharmaceutical Company's Remedy Proposal as Conditions for Approving the Concentration Was Lawful

At the time of the review of the Concentration in Question, the Provisions on the Review of Concentration of Undertakings had already taken effect. Article 39 (2) of these Provisions stipulates SAMR shall assess the effectiveness, feasibility, and timeliness of the Remedy Proposal. Article 42 (1) stipulates for a concentration of undertakings that may have or may likely have the effect of eliminating or restricting competition, where the Remedy Proposal submitted by the undertakings participating in the concentration can effectively reduce the adverse effects of the concentration on competition, SAMR may make a decision approving the concentration subject to remedies. This indicates that, through the assessment of the effectiveness, feasibility, and timeliness of the Remedy Proposal, where SAMR determines that the proposal can effectively reduce the adverse effects of the concentration on competition, SAMR may accordingly make a decision approving the concentration subject to remedies.

In this case, Beijing X Pharmaceutical Company argued that the Remedy Proposal contained significant flaws and could not effectively reduce the adverse effects on competition. Regarding this, this Court holds that Beijing X Pharmaceutical Company's relevant grounds lack basis. In light of Beijing X Pharmaceutical Company's specific claims, this Court

addresses them as follows:

(i) The Imposed Remedies Are Effective.

(1) Regarding the Concern about Input Foreclosure of Batroxobin API. The remedies by XX Pharmaceutical Company and the post-concentration entity to terminate the exclusive agreement provisions can eliminate, at the source, XX Pharmaceutical Company's ability to implement input foreclosure. This will restore the openness for all parties in China to procure batroxobin API from DSM, thereby facilitating the reduction of intermediate links and improving economic efficiency. Simultaneously, except for self-use, ensuring production during the transition period for Beijing X Pharmaceutical Company, and fulfilling supply obligations to the divestiture buyer, XX Pharmaceutical Company and the post-concentration entity are prohibited from exercising resale rights. This prevents the de facto creation of exclusive sales rights for the API. Thus, the Remedy Proposal can eliminate XX Pharmaceutical Company's ability to implement input foreclosure.

(2) Regarding the Pass-through of Efficiency Gains from the Concentration in Question. XX Pharmaceutical Company and the post-concentration entity committed to ensuring the supply of batroxobin injection in clinically common specifications after completing key personnel changes and reducing the selling price to medical institutions by no less than 20% of the current listed price. The efficiency gains from the Concentration can reduce patient expenditures and save medical insurance funds. That is, the Remedy Proposal can ensure that the efficiency gains from eliminating double marginalization are passed on to consumers. Furthermore, the Remedy Proposal explicitly states that XX Pharmaceutical Company will guarantee the supply of batroxobin injection in clinically common specifications, prevent the drug from being included in the National Drug Shortages List or the Key Monitoring List for Clinically Essential and Easily Shortaged Drugs, and may only reasonably increase the listed price of batroxobin injection due to increased production costs caused by exchange rate fluctuations or raw material price changes, and any increase shall not exceed the actual rise in production costs. That is, XX Pharmaceutical Company cannot raise prices because batroxobin injection is listed on the Drug Shortages List. Simultaneously, there is insufficient evidence to prove that XX Pharmaceutical Company has the ability to manipulate API cost increases. Furthermore, the fulfillment of the Remedy Proposal is subject to strict supervision by SAMR and the supervisory trustee. Under this rigorous supervision procedure, the determination of

whether a specific circumstance constitutes "unforeseeable events caused by factors beyond Simcere's control" is ultimately assessed and decided by SAMR. It is difficult for XX Pharmaceutical Company to circumvent its commitment obligations through artificial manipulation. Therefore, Beijing X Pharmaceutical Company's assertion—based merely on speculation—that XX Pharmaceutical Company could ultimately achieve price increases by manipulating API cost increases and supply shortages, thereby harming consumer welfare, lacks basis, and is not sustained by this Court.

(3) Regarding Concerns about Potential Entry. Firstly, XX Pharmaceutical Company and the post-concentration entity would divest all of XX Pharmaceutical Party's ongoing batroxobin injection R&D project. This remedy eliminates the horizontal overlap and potential competitive relationship between XX Pharmaceutical Company and Beijing X Pharmaceutical Company in the batroxobin injection market. Secondly, XX Pharmaceutical Company and the post-concentration entity would assume supply obligations for the API toward the divestiture buyer. Regarding price, they would supply the API to the divestiture buyer at the procurement price paid to DSM. Regarding quantity, during the divestiture buyer's R&D phase, they shall prioritize supplying the batroxobin API required for the divestiture buyer's R&D. After the drug is approved for marketing, except for factors beyond the control of XX Pharmaceutical Company and the post-concentration entity, they shall not refuse to supply batroxobin API to the divestiture buyer. This remedy ensures that the potential entrant is no less favorably positioned in obtaining batroxobin API than XX Pharmaceutical Company would have been if the Concentration in Question had not occurred. Thirdly, XX Pharmaceutical Company and the post-concentration entity would provide necessary assistance to facilitate the establishment of a direct batroxobin API supply relationship between the divestiture buyer and DSM. The aforementioned remedies secure the divestiture buyer's procurement source for batroxobin API and are conducive to promoting the advancement of R&D. In summary, the Remedy Proposal safeguards the procurement sources for batroxobin API for both the divestiture buyer and potential entrants.

(4) Regarding the Alternative Proposal. Firstly, regarding the purpose of establishing the alternative proposal, it may not necessarily be triggered, but serves to urge XX Pharmaceutical Company to complete the divestiture and terminate the exclusivity arrangement expeditiously, thereby resolving potential competitive harm. This facilitates the restoration of openness for

procurement from DSM by all parties in China and reduces intermediate links. Secondly, regarding the effect of implementing the alternative proposal, it stipulates that if the primary proposal cannot be implemented, the price of batroxobin injection shall be reduced by no less than 50% of the current price after completing key personnel changes. The primary proposal aims to stimulate market competition and reduce the price of batroxobin injection by promoting the market entry of generic versions, thereby increasing consumer welfare. Compared to the more indirect competitive price reduction under the primary proposal, the alternative proposal can directly achieve a substantial price reduction. In terms of the price paid by consumers, it is more effective than the primary proposal. The alternative proposal requires the post-concentration entity to adopt a price charged by undertakings in a near-competitive market, which is conducive to protecting consumer welfare and can address potential competitive harm. Beijing X Pharmaceutical Company's assertion that the alternative proposal improperly grants XX Pharmaceutical Company an opportunity to monopolize the market and may negatively impact the output, quality, and supply of batroxobin injection lacks factual basis, and is not sustained by this Court.

In summary, the Remedy Proposal can eliminate XX Pharmaceutical Company's ability to implement input foreclosure, pass on to consumers the efficiency gains from eliminating double marginalization, secure the procurement sources for batroxobin API for the divesting parties and potential entrants, and employ an alternative proposal that is stricter than the primary proposal. Therefore, the imposed remedies are effective.

(ii) The Imposed Remedies Are Feasible.

The fulfillment of certain obligations involves cooperation from third parties. To prevent XX Pharmaceutical Company from using third parties as an excuse to delay fulfilling its obligations, SAMR established a stricter alternative proposal. If the exclusive agreement provisions are not terminated on time, the divestiture is not completed on time, or the divestiture buyer fails to initiate R&D on schedule, then the stricter alternative proposal applies. This can effectively urge XX Pharmaceutical Company and the post-concentration entity to fulfill their obligation to terminate the exclusive agreement, seek a qualified buyer, and establish "dual safeguards" for the implementation of the Remedy Proposal. Beijing X Pharmaceutical Company argued that the Remedy Proposal's adoption of a price regulation approach and the use of the phrase "commercially reasonable efforts" lack feasibility for

supervision. Regarding this, this Court holds that:

On one hand, from the perspective of legal provisions, the Pricing Law of the People's Republic of China (hereinafter referred to as the "Pricing Law") and relevant laws and regulations indicate that price regulation refers to the state's activities of managing, supervising, and undertaking necessary adjustments and controls over the prices of goods and services. Its purpose is to safeguard the normal operation of the market while protecting national interests, enhancing economic efficiency, and safeguarding the legitimate rights and interests of consumers and business entities. Common price regulation measures include government-guided prices, government-set prices, price monitoring, price adjustments, and anti-price fraud, among others. Evidently, the Remedy Proposal (including the alternative proposal) essentially constitutes a price-related condition within the meaning of the Anti-Monopoly Law. Its purpose is to fully pass on the efficiency gains from the concentration to consumers, rather than a price regulation measure in the sense of the Pricing Law. On the other hand, from the perspective of factors assessed in the competitive impact evaluation of a concentration of undertakings, the price of goods and services directly affects consumer welfare and is a crucial dimension for evaluating the competitive impact of a concentration. It is not improper for the anti-monopoly enforcement agencies to adopt price-related remedies as one of the means to address competition concerns. Article 35 (1) of the Provisions on the Review of Concentration of Undertakings, which states that "the impact of the concentration of undertakings on consumers may be assessed in terms of price, among other aspects," corroborates this view. Furthermore, within the Remedy Proposal, the phrase "commercially reasonable efforts" appears only in two instances, both corresponding to specific actions. SAMR can determine whether XX Pharmaceutical Company has fulfilled its obligation to exert "commercially reasonable efforts" based on examining the completion of these specific actions and considering the concrete factual circumstances. This does not constitute the "being not amenable to supervision" alleged by Beijing X Pharmaceutical Company. In summary, Beijing X Pharmaceutical Company's relevant claims lack factual and legal basis, and are not sustained by this Court. The remedies by XX Pharmaceutical Company are feasible during the implementation process.

(iii) The Imposed Remedies Are Timely.

Firstly, the Remedy Proposal takes effect upon announcement. After the effective date,

XX Pharmaceutical Company itself must timely fulfill its obligations, such as terminating the exclusive agreement with DSM and divesting the relevant business. Given that the clinical trial approval certificates held by XX Pharmaceutical Company have time limits, the alternative proposal designates failure to complete the divestiture by a specified time point as one of the triggering conditions, leaving the divestiture buyer sufficient time to undertake preparatory work such as changing the trial license sponsor and preparing implementation plans. Secondly, XX Pharmaceutical Company and the post-concentration entity committed to immediately fulfilling the obligations to reduce prices and ensure supply upon completing key personnel changes. This prevents XX Pharmaceutical Company from using the excuse of lacking actual control for an extended period to avoid fulfilling its supply guarantee and price reduction obligations, urging it to fulfill its obligations promptly upon obtaining control of Beijing X Pharmaceutical Company. Thirdly, XX Pharmaceutical Company and the post-concentration entity committed to immediately reducing prices for new sales orders signed after completing key personnel changes and to applying for a reduction in the listed price within three months. This avoids delays in reducing the listed price caused by obstacles related to the eligibility criteria for price adjustments in the medical insurance system. Therefore, the remedies imposed on XX Pharmaceutical Company are timely. Beijing X Pharmaceutical Company's claim that within one year after the Challenged Decision was issued, XX Pharmaceutical Company did not conduct the divestiture according to the Remedy Proposal and monopolized the market lacks factual basis and is not within the scope of this case's adjudication.

Furthermore, the evidence on record cannot prove that SAMR used the arbitration outcome as the basis for the Challenged Decision and the Challenged Reconsideration Decision. Nor is there evidence proving that the Challenged Decision was solely dictated by the views of experts and scholars. Regarding this litigation claim by Beijing X Pharmaceutical Company, this Court also declines to sustain it.

The Challenged Decision by SAMR was supported by conclusive evidence and correctly applied the law. The Challenged Reconsideration Decision, rendered on the basis of established facts, upheld the Challenged Decision and likewise possesses factual and legal basis. Its conclusion is correct and shall be affirmed according to law.

In summary, both the Challenged Decision and the Challenged Reconsideration Decision

clearly established the facts, correctly applied the law, and followed lawful procedures. The litigation claims of Beijing X Pharmaceutical Company lack factual and legal basis, and are not sustained by this Court. In accordance with the provisions of Article 69 of the Administrative Procedure Law of the People's Republic of China, the judgment is as follows:

The litigation claims of the Plaintiff, Beijing X Pharmaceutical Company, are dismissed.

The case acceptance fee of fifty yuan (RMB) shall be covered by the Plaintiff, Beijing X Pharmaceutical Company. (Already paid)

If dissatisfied with this judgment, the parties may, within fifteen days from the date of service of this judgment, file an appeal with this Court by submitting a petition for appeal and copies according to the number of opposing parties, prepay the appeal acceptance fee of fifty yuan (RMB), and appeal to the Supreme People's Court of the People's Republic of China.

Presiding Judge: Xie Zhenke

Judge: Li Yingxin

Judge: Liu Xinlei

December 30, 2024

Judge's Assistant: Luo Mingxin

Clerk: Liu Po