

Highlights of the Anti-monopoly Guidelines in the Field of Active Pharmaceutical Ingredients

Introduction:

Drug issues have a direct bearing on people's health and life safety, and are fundamental to the national economy and the people's livelihood. It goes without saying that active pharmaceutical ingredients ("APIs") used in the manufacture of drugs are important to the drug industry. As such, in recent years, the antitrust enforcement authorities have been paying close attention to the field of APIs, and have investigated and dealt with several API-related monopoly cases involving, among others, pralidoxime chloride, glacial acetic acid, chlorpheniramine, and calcium gluconate.

On the basis of integrating the anti-monopoly law enforcement experience in the field of APIs, the State Administration for Market Regulation ("SAMR") drafted and promulgated the *Anti-monopoly Guidelines in the Field of Active Pharmaceutical Ingredients (Draft for Comment)* on October 13, 2020, seeking public comments. On November 15, 2021, the Anti-monopoly Commission of the State Council officially promulgated the *Anti-monopoly Guidelines in the Field of Active Pharmaceutical Ingredients* ("APIs Guidelines"), which becomes China's third industrial antitrust guidelines in succession to the *Anti-monopoly Guidelines in the Field of*

Automobile Industry ("Automotive Guidelines") and the *Anti-monopoly Guidelines in the Field of Platform Economy* ("Platform Guidelines").

On the basis of the behavior patterns, operation characteristics, cooperation modes, etc., of the operators in the field of APIs, the APIs Guidelines specifically detail the analysis methods and identification factors for monopolistic conducts in the field of APIs, which provides clearer guidance for the lawful and compliant operation of operators in the field. This article will sort out the key points of the APIs Guidelines in light of the antitrust enforcement cases in the field of APIs in recent years and with reference to other industrial guidelines, and expects to provide some inspiration for the antitrust compliance of API enterprises.

I. Analytical principles for relevant market definition in the area of APIs are established

1. Basic analytical framework for market definition in the area of APIs

The APIs Guidelines follow the general principles established for the definition of relevant markets in the *Anti-monopoly Law* ("AML") and the *Guidelines of the Anti-Monopoly Commission of the State Council on the Definition of Relevant Markets*, i.e., to define the relevant market under the basic

analytical framework of substitutability analysis, from both demand and supply substitution perspectives. Pursuant to the APIs Guidelines, an API will generally constitute a separate relevant product market, which may be further subdivided on a case-by-case basis (e.g., according to quality grade of drugs, scope of application, etc.), because of their special roles in the production of drug products; meanwhile, if there is a substitution relationship between different types of APIs, it may be recognized that these types of APIs constitute one single relevant product market as the case may be.

2. API markets can be further segmented into API production markets and API distribution markets

The APIs Guidelines provide that the product market for APIs may be further segmented into production markets and distribution markets, where applicable. Since the customer groups may differ between the API manufacturing process and the API sales process, it is more reasonable to define different relevant product markets on the basis of different industry chain processes. This market definition approach is consistent with the past legislation and law enforcement practice. For example, the Automotive Guidelines make it clear that auto wholesale and auto retail may need to be defined as separate markets where applicable; in addition, in the abuse of market dominance case by Nanjing Ningwei Pharmaceutical Co., Ltd. published on November 18, 2021 (the "**pralidoxime chloride case**"), the relevant product market was defined as the sales/distribution market of phosgene chloride APIs.

Defining the production and distribution of APIs as separate relevant markets reflects the concern of anti-monopoly law enforcement authorities on different stages of the same industry chain in key law enforcement fields, and also reminds business

operators that they shall assess their market forces at different stages of the industry chain separately, so as to analyze and judge the anti-monopoly risks in their business operation more accurately.

3. Generally, the relevant geographic market for APIs is the domestic market of China.

Due to the uniqueness of the API industry, its geographic market definition is different from that of the automotive and internet industries. The Automotive Guidelines specify that the geographic market for the wholesale of passenger vehicles is country-specific; however, at the retail level, the geographic market for passenger vehicles may be defined as provincial or regional wide due to various regional restrictions such as automobile license plates, automobile permit, after-sale services and warranty clauses, etc.; the Platform Guidelines provide that, in light of platform characteristics, the relevant geographic market is generally defined as China national market or a specific regional market, or may also be defined as global where applicable.

With respect to the geographic market definition for APIs, it should be noted that the qualifications and regulatory standards relating to the production and distribution of APIs vary country to country. An operator engaging in the production and distribution of APIs in China shall organize its production according to the approved process in China, and strictly abide by the Good Manufacturing Practice (GMP) for Pharmaceutical Products and the Good Supply Practice (GSP) for Pharmaceutical Products in China, so as to ensure that the production and operation processes comply with the country's statutory requirements; and imported APIs shall be approved by relevant Chinese regulators. Therefore, the relevant geographic market for the production and distribution of APIs is generally defined as China national. In the currently available API enforcement cases, the anti-monopoly law

enforcement agencies have all defined the relevant geographic market as China.

II. The conducts of horizontal monopoly agreements are specified.

Article 13 of the AML prohibits the conclusion of horizontal monopoly agreements by competing undertakings. By considering the characteristics of the API industry, the APIs Guidelines provide a concrete list of those specific conducts of API operators that constitute horizontal monopolistic agreements, and also provide further clarifications on concerted conducts.

1. It is prohibited to conclude horizontal monopoly agreements under the disguise of agreements on joint production, joint purchase, joint sales and joint bidding

Article 6 of the APIs Guidelines provides that, where an API manufacturer and its competitors negotiate to determine the production quantity, sales quantity, sales price, sales target, sales territory, etc. of APIs through joint production agreement, joint procurement agreement, joint sales agreement, joint bidding agreement or otherwise, such agreements generally constitute horizontal monopoly agreements prohibited by the AML.

On the surface, this provision seems to differ to some extent from the attitude towards horizontal cooperation agreements set forth in the Automotive Guidelines. The latter stipulates that certain horizontal cooperation agreements, if satisfying certain conditions, can actually improve economic efficiency, thereby promoting competition and increasing consumer welfare, and thus can be exempted in accordance with Article 15 of the AML. However, in our view, the horizontal cooperative agreements listed in the APIs Guidelines do not necessarily constitute a horizontal monopolistic agreement, and there is no contradiction between the APIs Guidelines and the Automotive Guidelines

with respect to their positions thereon. In essence, it is the practices of "horizontal monopoly agreements under the guise of horizontal cooperation", i.e., to achieve synergies in terms of production quantity, sales quantity, sales price, target customers and sales territory of APIs through horizontal cooperation agreements, that is restricted by the APIs Guidelines. There is still the possibility that an exemption can be granted on a case-by-case basis for true horizontal cooperation agreements between API competitors in accordance with Article 15 of the AML.

However, it is noteworthy that given the importance of APIs to people's livelihood, and the fact that the possible procompetitive effects of horizontal collaborative agreements are not addressed in the APIs Guidelines, we tend to believe it may be more difficult to obtain an exemption in accordance with Article 15 for API operators entering into horizontal cooperation agreements. Therefore, API operators should fully evaluate the antitrust risks before entering into such agreements.

2. The communication of sensitive information involves a high risk of horizontal monopoly agreements

The APIs Guidelines provide that where "API manufacturers communicate and coordinate with each other sensitive information such as sales prices, capacity and output, and production and sales plans of APIs through a third party (such as an API distributor or a downstream drug manufacturer), trade fairs, industry conferences, etc.", and where "API distributors communicate and coordinate with other competing API operators in respect of purchase quantity, procurement targets, sales price, sales quantity, sales targets, etc.", such conducts generally constitute horizontal monopoly agreements.

As such, competing API operators shall not communicate or coordinate sensitive information by

any means. Neither direct communication among competing operators nor their coordination through third parties is allowed. In particular, where sensitive information is exchanged through third parties, even though such third parties may not be competitors in the industry, they may still be regulated by the hub-and-spoke agreements as described below.

3. API operators are prohibited from entering into horizontal monopoly agreements not to manufacture or sell APIs

The APIs Guidelines specifically point out that if an API manufacturer reaches an agreement with a competing API operator that it will not produce or sell APIs in exchange for compensation from the latter, such agreements generally constitute horizontal monopoly agreements.

Essentially, the conduct described in this article belongs to the restriction of production/sales volume or market segmentation which is prohibited by Article 13 of the AML. To compensate operators who commit not to manufacture or market APIs is, in effect, a way to eliminate the competition in the market for the manufacture or sale of APIs. This is similar to the monopolistic practice of "reverse payment"¹ in the pharmaceutical industry.

4. Hub-and-spoke agreements are specifically put under governance

Competing API operators may reach hub-and-spoke agreements which have the effect of horizontal monopoly agreements by virtue of their vertical relationship with other operators or under the

¹ "Reverse payment" means that a patented drug manufacturer pays a certain form of economic benefits to a generic drug manufacturer, and in return, the generic drug manufacturer undertakes to the patented drug manufacturer to delay the entry of its generic drugs into the market.

organization and coordination of other operators. Article 9 of the APIs Guidelines specifies that an operator shall not organize API operators to reach monopoly agreements or provide them with substantial assistance for reaching monopoly agreements. This provision corresponds to the rule on hub-and-spoke agreements in the Platform Guidelines, and also echoes Article 18 of the recently issued Amendment to the AML.

It should be noted that the "subjective intention" of an API operator is a major factor to be considered in determining whether it should be held guilty of a hub-and-spoke conspiracy² misconduct. For example, if an API operator is aware or should have been aware that certain other competing operators have entered into identical, similar or coordinated agreements with the same API distributor but still chooses to enter into such agreement with the same distributor, it will face the risk of horizontal monopoly agreements; however, if the API operator is not aware of the conclusion of similar agreements by other operators when entering into the relevant agreement with the distributor, it may claim that its behavior does not constitute a horizontal monopoly agreement. Nonetheless, the APIs Guidelines do not provide a clear explanation as to how to define "should have been aware" or "be aware", and thus leaves certain discretion to the anti-monopoly enforcement agencies. Based on such, we suggest that API operators shall properly handle the relationship with API distributors and other API operators when entering into agreements with API distributors, so as to avoid, as far as possible, being

² "Hub-and-spoke conspiracy" refers to the phenomenon that two or more operators with a competitive relationship (spokes) each communicate sensitive information with other operators, intermediaries, third-party platforms and others that do not have a direct competitive relationship with them (hubs), and reach competitor conspiracy under the good offices and coordination of the "hubs".

identified as having entered into hub-and-spoke agreements with other operators due to "negligence".

5. Indirect Evidence can be adopted to identify concerted conducts

According to Article 8 of the APIs Guidelines, direct evidence may be used to determine whether concerted conducts have been taken in the field of APIs. If direct evidence is difficult to obtain, logically consistent indirect evidence may be relied upon to determine whether business operators are aware of the relevant information and whether there are concerted conducts among such operators in accordance with Article 6 of the *Interim Provisions on Prohibition of Monopoly Agreements*.

According to Article 6 of the *Interim Provisions on Prohibition of Monopoly Agreements*, the following factors shall be considered in identifying concerted conducts: (1) whether there is consistency in the market conducts of business operators; (2) whether there has been communication of intention or information exchange between business operators; (3) whether business operators can give reasonable explanation for their concerted conducts; and (4) market structure, competition status and market changes, etc. of the relevant market.

Generally, the intention liaison and information exchange between operators are highly concealed, and thus it is difficult for law enforcement agencies to obtain them. However, the market conducts of business operators, market structure and competition status are relatively easy to find out. According to the provisions on indirect evidence in the APIs Guidelines, the anti-monopoly enforcement agencies may identify concerted conducts between business operators based on the consistency of their market conducts in combination with other indirect evidence.

It is noteworthy that Article 5 of the APIs Guidelines provides, parallel conducts such as price leadership by business operators based on independent expression of intentions do not fall within the scope of concerted conducts. Therefore, in case of an anti-monopoly investigation arising from the consistency of their market conducts, it is possible for API operators to interpret/defend from the perspective of, among others, independent expression of intentions.

III. Vertical regulation of customer restrictions and geographical restrictions is strengthened

As far as vertical monopoly agreements are concerned, resale price maintenance has always been the focus of anti-monopoly enforcement agencies. The APIs Guidelines list the specific forms of resale price maintenance by API manufacturers in practice, which do not differ significantly from other industries.

As regards customer restrictions and geographical restrictions, according to the APIs Guidelines, geographical restrictions mean that an API operator restricts its trading counterparties to only supply APIs to one or several downstream API distributors within specific distribution areas, and the downstream API distributors shall not sell to other distribution areas; customer restrictions refer to that an API operator restricts its trading counterparties to only sell or not sell APIs to specific API distributors or drug manufacturers.

Customer restrictions and geographical restrictions are regulated under both the vertical monopoly agreement and the abusive conduct of imposing unreasonable transaction conditions. As a result, the antitrust risks involved are analyzed under the vertical monopoly agreement framework and the abuse framework respectively:

From the perspective of abuse of dominant market position, pursuant to Article 19 of the APIs Guidelines, an API operator with dominant market position shall not impose unreasonable restrictions on the sales areas and sales targets of APIs or drugs. Therefore, an API operator with dominant market position, if implementing geographical restrictions and customer restrictions, will face the risk of the abusive conduct of imposing unreasonable transaction conditions.

From the perspective of vertical restraints, where an API operator does not have market dominance, its customer restrictions and geographic restrictions may still face the risk of vertical monopolistic agreements. Article 7 of the APIs Guidelines provides that the imposition of geographical or customer restrictions by an API operator may constitute a monopoly agreement prohibited by Article 14 of the AML. Geographical and customer restrictions may lead to market segmentation and price discrimination, weaken competition in API markets, and may also make it difficult for other API distributors or drug manufacturers to obtain supply of relevant products, keeping the prices of APIs and drugs at a high level.

From the above provisions, it can be seen that, even under the framework of vertical monopolistic agreements, the APIs Guidelines emphasize the anticompetitive risks of geographical and customer restrictions, rather than adopting the regulatory attitude in the Automotive Guidelines, which exempt those geographical and customer restrictions that are set up by operators without significant market power and that are economically efficient and have justifiable reasons. This, to some extent, reflects the strict regulatory attitude of the anti-monopoly enforcement agencies towards the geographical or customer restrictions in the API industry.

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Although there have been no penalty cases directly related to customer restrictions or geographical restrictions in China by now, some penalty decisions have reflected the anti-monopoly enforcement agencies' concern about the anti-competitive effects of customer restrictions and geographical restrictions. For example, in the vertical monopoly agreement case of Yangtze River Pharmaceutical Group, the enforcement agency held that "the company further strengthened the mandatory and punitive nature of the [resale price maintenance] agreement by restricting sales areas, prohibiting cross-supply of products between different sales areas, and imposing penalties for breach of contract, etc., so that the distributors were left with no choice but to comply with its pricing requirements."

Based on such, under the analytical framework of the APIs Guidelines, it is necessary for API operators to specifically analyze the necessity and anti-competitive effects of the customer or geographical restrictions they plan to set, so as to avoid the risk of vertical monopoly agreements or the abuse of dominant market position to the extent possible.

IV. Detailed specifications are provided on the identification of market dominance and the common abusive conducts in the API field

With respect to the abuse of dominant market position in the API field, the APIs Guidelines generally follow the analytical framework provided in Chapter III of the AML and in the *Interim Provisions on the Prohibition of Abuse of Dominant Market Position*, but provide further details in terms of the identification of dominant market position and the common abusive conducts in light of the characteristics of the APIs industry.

1. The proportion of sales of a manufacturer

controlled by a distributor is listed as one factor to consider in evaluating the latter's market share

On top of sales figures, actual capacity and output of an operator, competition status in the relevant market and other customary factors to consider in determining an operator's market share as stipulated in the AML, the APIs Guidelines further provide that in the calculation of the market share of an API distributor, in addition to sales value, sales volume and inventory, the proportion of the sales volume of a manufacturer that is controlled by the distributor may also be taken into account. We believe that this largely derives from the exclusive distribution pattern that is commonly seen in the API industry.

The latest antitrust enforcement practice shows that it is highly likely that an exclusive distributor will be found to have dominant market position. For instance, in the pralidoxime chloride case, the company entered into an exclusive distribution agreement with the only one existing API manufacturer in the market, and was thus deemed to have 100% market share in the sales market of pralidoxime chloride APIs and was accordingly presumed to have dominant market position therein.

2. The criteria for assessing collective market dominance is further clarified

It is clearly stipulated in Article 22 of the APIs Guidelines that " when two or more API operators share responsibilities and cooperate with each other to implement the monopolistic conduct stipulated in this chapter, it may constitute abuse of collective dominance. In determining that two or more API operators have a dominant market position, consideration shall be also given to factors such as market structure, transparency of the relevant market, degree of homogeneity of relevant products, and consistency of the operators' behaviors."

According to the dominant academic views and the practice in other jurisdictions, collective market dominance is not determined purely on the basis of

market share. Collective market dominance is primarily found in oligopoly markets, which requires each oligarch to act independently in the absence of explicit collusion but to maintain a tacit understanding of reducing the competition between them based on the anticipation of the conduct and strategies of other competitors. Generally speaking, in the absence of the guarantee of concerted conducts, such tacit understanding is very unstable, and thus there are strict market and economic condition requirements for the formation of collective market dominance.

Neither the AML nor the existing anti-monopoly law enforcement practice provides a clear standard for the determination of collective dominant position. The APIs Guidelines makes a breakthrough on top of the relevant existing principle-like rules, and enhances the predictability of anti-monopoly law enforcement, which therefore is undoubtedly of great significance for the compliance operation of enterprises.

3. The common abusive practices in the API field are specifically listed

Article 14 of the APIs Guidelines specifies those common abusive conducts in the API area, including, among others, selling APIs at unfairly high prices, refusing to trade with counterparties, imposing exclusive transaction limitations on counterparties, conducting tie-in sales or imposing unreasonable trading conditions, and implementing discriminatory treatment on counterparties with the same conditions, etc.

The APIs Guidelines provide clear guidance on the factors to be considered in determining each type of abusive conduct, which enhances the operability of the rules and provides market players with clear compliance guidance. Taking unfairly high price as an example, in order to analyze whether an unfairly high price is charged, the following factors may be considered: whether the selling price is significantly higher than that of other competitors, the selling

price of the business operator in other territories, and the extent of increase in the selling price of APIs. For example, in the pralidoxime chloride case, the anti-monopoly enforcement agency believed that the company's sales price of pralidoxime chloride was apparently unfair: firstly, from the perspective of price increase, the company's sales price was 5-10 times of its purchase price; secondly, from the aspect of historical price, the company's sales price in 2018-2019 (when the company has obtained market dominance) was 26.09-52.17 times of its sales price in 2014. Based on such, the company was found to have implemented the abusive conduct of charging unfairly high price.

Conclusion

Given that the API industry has small number of competitors, high market concentration and high

market entry barriers, it faces relatively greater antitrust risk compared with other industries. The promulgation of the APIs Guidelines will enhance the predictability and transparency of the law enforcement activities in this industry, and will also bring benefits to API business operators in delimiting their conduct boundaries. From the perspective of enterprise compliance, we recommend that API business operators conduct a comprehensive review and self-examination of their business models and business activities in accordance with the APIs Guidelines as soon as possible, and establish a feasible anti-monopoly compliance system, so as to adapt to the new market system and regulatory environment as far as possible and ensure the compliance of their own operation.

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