PharmAsia News

September 22, 2008

Insider Analysis From Sidley Austin LLP: Market Definition In Life Sciences Sector Under The Chinese Anti-Monopoly Law

By Chen Yang and Adrian Emch, Sidley Austin LLP, Beijing

China's Anti-Monopoly Law in force since Aug. 1 raises difficult questions for market players in the health care industry in China. One issue of particular importance is how to define the "relevant market" for medical products.

The definition of a relevant market affects two key areas - (1) mergers and acquisitions, and (2) distribution and sales agreements. Both the merger control system established by the AML and its provisions on "abuses of dominant market positions" revolve around the relevant market concept. When China's Ministry of Commerce examines a merger, acquisition or possibly even certain types of joint ventures, it will look at the transaction's impact on competition in the relevant market.

Similarly, before alleging that a company has abused a dominant position, the National Development and Reform Commission, the State Administration of Industry and Commerce, or a plaintiff in a private suit must show that the defendant is dominant in a relevant market. Needless to say, the definition of the relevant market can be *the* decisive element in both MOFCOM's decision to approve a merger or NDRC's or SAIC's finding that an abuse of a dominant market position has been committed.

Although the AML contains little information on market definition, it nonetheless provides some limited guidance. By indicating that the relevant market must be defined according to the product scope and the geographical scope, the AML in principle follows the traditional approach taken by the United States and the European Union. Market players in China may seek guidance from the laws in these jurisdictions - especially before any rules implementing the AML on this issue become available for further guidance.

A Recommended Approach

The basic issue underlying market definition is whether two products are substitutable in the eyes of the consumer. For example, regulators frequently ask themselves whether a 5 percent or a 10 percent price increase imposed by a hypothetical monopolist of product A would be profitable, or whether demand would shift to other products, making the price increase unprofitable. If the former holds true, then product A constitutes its own relevant market. If the latter scenario prevails, the market is broader than product A.

In order to render this hypothetical example operational, regulators tend to examine certain factors that may influence potential shifts in consumer demand in the event of a price increase. For example, those factors can be product characteristics, intended use, price levels, production processes and distribution channels.

For the health care industry, U.S. law follows a traditional case-by-case approach, which also applies in other industries. In recent enforcement actions, U.S. agencies have examined whether drugs treat the same disease, condition or indication; have the same "mechanism of action" chemical compounds; form, frequency or strength of dosage; whether they are branded or generic; are currently marketed or are in development; and require a prescription or are sold over-the-counter.

In contrast, EU law contains a sort of "rule of thumb," which might provide more practical guidance to pharmaceutical and medical device companies in China for defining the relevant market. The European Commission frequently uses the Anatomical Classification by the European Pharmaceutical Market Research Association (EphMRA) as a starting point to define the relevant market for medicines. The market definition generally is made at the third level of the classification (ATC 3). Although the ATC is meant only to be a starting point, the European Commission rarely departs from this EphMRA classification.

The Chinese government agencies and courts are unlikely to resort to a classification made by a European association. However, they might look at similar classifications existing in China, such as those made by the Ministry of Labor and

Social Security for the purpose of social security reimbursements. Like the EphMRA classifications, the classifications by MOLSS also go into considerable detail, and have several levels.

If the Chinese authorities and courts accepted such rules of thumb by referring to the existing MOLSS classifications or by developing similar classifications, the antitrust self-assessment by life science companies would become simpler, and predictability would increase. Of course, as in the EU, classifications are not perfect substitutes for a more comprehensive analysis of the actual market conditions. To obtain increased certainty about the accuracy of their market definition, companies in China may need to resort to more sophisticated techniques for market definition. For example, measuring cross-price elasticity between potentially competing products or exploring price differentials or a correlation between them might give insight into the proper definition of the relevant market.

With reliable rules of thumb - and after conducting an in-depth factual analysis for each product - life science players will achieve higher levels of certainty that their conduct *vis-à-vis* distributors is legal, and will be able to better anticipate whether a planned merger or acquisition is likely to get approval from MOFCOM.

Geographic Scope Of The Market

As the plain language of the AML indicates, the geographic scope of the relevant market will be an equally important element in defining the relevant market.

In practice, the geographic scope of health care markets can be influenced by the intensity of regulation at the various levels of governance. Detailed regulation may mean that the market conditions are distinct from other places and can work as a market entry barrier. While regulation of the health care industry is most intense on the national level in China, in some areas certain local governments and their agencies also exert significant regulatory powers - in law or in practice.

Other factors also can play an important role in the determination of the relevant geographic market. For example, high transportation costs would make it more expensive for consumers to switch to suppliers located in other countries, so that a price increase by local suppliers would be profitable. This factor would indicate that the market is national.

Moving Forward In China

Although the EU experience can provide some guidance in the absence of any measures implementing the AML on this issue, it is clear that there are limits to its usefulness in China because China's regulatory system and the preferences of its consumers may differ greatly from the EU. Some of the methodological tools used in the U.S. and the EU will be helpful for companies in China, but the *outcome* of the market definition analysis in China may not necessarily be the same as in those jurisdictions.

Companies in the health care industry should identify possible classifications that could serve as useful rules of thumb in China, and perhaps should seek the views of China's competition authorities on this issue. Active participation in possible public consultations on future rules implementing the AML also may provide an opportunity to influence the authorities' approach to market definition. Companies with particularly far-reaching distribution policies may want to consider conducting an in-depth legal and economic market definition analysis for their products.

Chen Yang is a partner in the firm's Beijing office, where she heads the firm's China Life Sciences Practice. Ms. Yang's practice focuses on regulatory, corporate and commercial law, including Intellectual Property and Antitrust aspects of life sciences matters.

Adrian Emch is an associate in Sidley's Beijing office, where he focuses on competition, trade and regulatory law.