Biotech Mergers and Acquisitions, and the Antitrust Risk

by Anjana Patel and Patricia Wagner

The biotechnology industry has seen an upsurge in mergers, acquisitions and consolidation transactions (hereinafter consolidation transactions) over the last several years. The reason, in part, for this uptick is because of the pressures biotechs face to ensure they develop a deep product pipeline with a high potential for commercialization. As a result, the success and long-term sustainability of any biotechnology company is dependent on obtaining funding to push through more research and development, as well as obtaining advanced expertise in regulatory compliance and sales and marketing from other more established biotechs or big pharma. At the same time, there has been increasing interest from investors in buying biotechs with pipelines of emerging products that have a potential of reduced research and development time, and thus expedited time to market. This mutual demand has created a highly competitive deal market as more and more biotechs are being bought and sold.

Many biotechs view the upward trend in these consolidation transactions as an opportunity to gain more scale and leverage to successfully compete and thrive in this environment. However, biotechs should be aware of the legal and regulatory prohibitions associated with these transactions, especially the potential risk under the antitrust laws. This article discusses some of the major risk areas under the federal antitrust laws.

The Federal Antitrust Laws

The foundation of federal antitrust scrutiny and enforcement rests on two main laws—the Sherman Act[1] and the Clayton Act.[2] The prohibitions in these laws are summarized below.

The Sherman Act

Section 1 of the Sherman Act makes it illegal for two or more independent firms to enter into an agreement that unreasonably restrains trade or commerce. A Section 1 violation requires an agreement between separate entities. Under Section 1, agreements are divided into two general categories: those that are judged under the 'rule of reason' and are prohibited only if their overall impact is anticompetitive, and those that are deemed so likely to have an anticompetitive effect that they are deemed illegal '*per se*,' regardless of their actual impact on competition. Conduct deemed *per se* illegal sometimes results in individual criminal indictments.

For purposes of Section 1, an agreement need not be written or explicit. An oral agreement, a tacit agreement, or a so-called 'understanding' can suffice to create liability under Section 1. Moreover, an agreement can sometimes be inferred from the parties' conduct, even in the absence of direct evidence of an agreement. As a result, parties contemplating a consolidation transaction need to be particularly aware of Section 1, because even the exchange of competitively sensitive information during contract negotiations and in due diligence could be viewed by an enforcement authority as an agreement between competitors.

The Clayton Act

Section 7

Section 7 of the Clayton Act[3] prohibits mergers that are likely to reduce competition if the transaction is completed. In order to determine if a merger will have an adverse effect on competition, the antitrust enforcement agencies have to determine the appropriate geographic market and the appropriate product market, and then determine the likely anticompetitive effect in those markets. The agencies obtain some relevant information on the potential markets from the parties' Hart Scott Rodino (HSR) form submissions; however, the agencies may also conduct interviews with other market participants and customers to determine the likely impact of any merger.

The Hart Scott Rodino Act—Amending the Clayton Act

The Hart Scott Rodino Act[4] requires parties to a consolidation transaction of a certain size provide notification of the transaction with the Federal Trade Commission (FTC) and the Department of Justice (DOJ). Under the current standards, a transaction requires notification if:

- as a result of the transaction, the acquiring entity would hold "an aggregate total amount of the voting securities and assets of the acquired person" in excess of $323 million;[5] or
- as a result of the transaction, the "acquiring person would hold an aggregate total amount of the voting securities and assets of the acquired person" in excess of $80.8 million and the transaction meets the size of person test below.[6] The value of assets to be acquired is generally the fair market value of the assets or the acquisition price, whichever is greater.[7] Equity deals are treated (for HSR purposes) as asset transactions.

As noted above, if the size of the transaction is more than $80.8 million but less than $323 million, the transaction is reportable if it meets the size of person test. The size of person test is applied to the entire acquiring person, and is applied to the entire acquired person (*i.e.*, not just the entities involved in the transaction).

The size of person test is met if:

- A person that has voting securities or total assets of $16.2 million or more is being acquired by any person that has total assets or annual net sales of $161.5 million or more; or
- A person that has voting securities, annual net sales or total assets of $161.5 million or more is being acquired by any person that has total assets or annual net sales of $16.2 million or more.

In determining the size of the person, the focus of the HSR regulations is on the "ultimate parent entities." The ultimate parent entity is defined as an entity that is not controlled by any other entity.[6] In effect, one proceeds up the chain of control from the acquiring or acquired party to find the ultimate parent entity, and then down the chain of control from the ultimate parent entity to determine which entities are to be included in the 'person.' Thus, the size of the person includes the assets (and sales, where applicable) of all entities (foreign and domestic) included within the person.

Risk During Due Diligence

Information Exchange

As noted above, the antitrust laws apply not only to the actual transaction between competitors, but also to the parties' conduct during negotiations and due diligence. Thus, biotechs should be aware that exchanging certain information prior to the consummation of the transaction could subject the parties to antitrust scrutiny from the FTC or DOJ. In general, the antitrust laws require that the parties withhold confidential and proprietary information from each other as they would from any other competitor. In particular, parties must avoid sharing information that could be seen as facilitating price fixing or market allocation in the event the acquisition transaction does not occur.

Thus, even in the diligence process the parties must avoid sharing information that could be seen as facilitating price fixing or market allocation in the event the transaction does not occur. To the extent that a compelling need exists to exchange sensitive information, access to such information should be restricted to independent consultants and attorneys retained by the parties, or specific 'clean teams' set up for the transaction. The parties should execute an agreement that restricts the use of confidential information and limits access to certain information to certain individuals.

To enable the parties to genuinely evaluate the transaction in due diligence, and at the same time not run afoul of the antitrust laws, often much of this high-risk information will be subject to clean team review. This means the information may be limited for review only by counsel and third-party consultants of the target, and not by the business people or those in a position to use the information for the strategic advantage of the buyer. Counsel and the consultants then present the information, in a general, non-detailed way, to the business people of the buyer.

Independence

The antitrust laws also require that, until the transaction is consummated, the parties must continue to act as independent competitors. As noted above, the antitrust laws prohibit competitors from entering into certain types of agreements, including agreements on price and agreements not to compete.

However, as parties to a consolidation transaction begin to plan for transition, there will be a need to exchange information for planning purposes. The concern is that an antitrust enforcement authority could view such discussions as 'gun-jumping,' in other words, the parties are acting as a single entity prior to the transaction. Thus, such discussions should be limited to planning and should not be a forum for any party to dictate how the other party should conduct its business prior to the close of the transaction. Furthermore, the parties should not jointly implement any integration plans, such as closing or consolidating ancillary services, jointly negotiating vendor contracts, or consolidating administrative functions. While either party to a transaction may legitimately decide to postpone making such decisions, or take into account the pending transaction when making such decisions, the decisions must be made unilaterally.

There is some information, however, that can be exchanged without antitrust risk. Such information includes:

- Publicly available information
- Numbers, names, and titles of current employees
- Evaluations of current employees
- Current personnel assignments and duties
- Physical facility descriptions
- Information related to computer systems and management information systems
- Environmental information
- Pension and benefit plans
- Other general operational issues

Risk to the Transaction

In addition to the risk during the negotiation, due diligence and pre-closing transition phases described above, the transaction itself may pose antitrust risk because the parties are potentially competitors. As described above, depending on the size of the transaction, potentially competing parties seeking to enter into a consolidation transaction will be required to file notification to the FTC and DOJ under the HSR Act. As part of the HSR filing process, the parties must submit infor-

mation related to the markets in which they operate, and certain business documents created that evaluate the impact of the transaction on that market. The submission also requires the payment of a filing fee, the amount of which is dependent on the value of the transaction.[9]

Once filed, the agencies have 30 days to review the submission to determine whether the transaction requires further investigation to decide if it will have an anticompetitive effect on the relevant market. If the agencies determine the transaction does not require additional investigation, the 30-day waiting period closes without action.[10] If the agencies determine more information is needed, the reviewing agency can issue a second request, a process whereby the agency requests significant amounts of information from both parties to the transaction.[11] The parties may only close the transaction once the HSR waiting period has closed without further action by the agencies, or, in the event of a further investigation, when the investigation closes. Even if a transaction is not subject to an HSR filing, it can be reviewed by the antitrust agencies. In these cases, the FTC or DOJ may become aware of the transaction if competitors or customers in the market call an agency to request the proposed (or completed) transaction be investigated for its anticompetitive effect.

Antitrust Enforcement

With the increased deal activity in the healthcare and life sciences industry over the last several years, the FTC and the DOJ have been very active in scrutinizing and enforcing the antitrust laws, with the effect, in some cases, of forcing the parties to potential consolidation transactions to break up discussions and negotiations and, sometimes, abandon transactions all together.

Recently, there has been some question regarding whether this level of enforcement would change under the new administration. However, Maureen Olhausen, the FTC chairman, has said the FTC would continue to prioritize enforcement actions in the healthcare and pharmaceutical industries.[12] This is consistent with the FTC's recent enforcement action involving Valeant Pharmaceutical's acquisition of Paragon.[13] Both companies manufactured certain types of contact lenses and accounted for more than 70 percent of contact lens sales in the U.S. The FTC alleged the acquisition was anticompetitive, and that Valeant used the acquisition to increase prices and decrease discounts, innovation and product distribution options in each market. The FTC ordered that Valeant sell Paragon entirely to another entity. The FTC then held a public comment period on the order, which was recently concluded and resulted in an approval of the order.[14]

Conclusion

The upward tick in biotech consolidation transactions is likely to continue in the near future, especially as the industry becomes highly competitive. Biotechs that are well educated with the very real antitrust risk of engaging in a consolidation transaction in advance of entering into the transaction process will be at an advantage because ignorance of the impact of these laws could mean abandoning a consolidation transaction after much time, effort, resources and expense are invested in the process. ⚖

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ENDNOTES

1. 15 U.S.C. §1.
2. 15 U.S.C. § 18.
3. 15 U.S.C. § 18.
4. 15 U.S.C. § 18a.
5. 15 U.S.C. § 18a(a)(2)(A); 15 U.S.C. § 18a(a)(2)(B)(ii)(II).
6. 15 U.S.C. § 18a(a)(2)(B).
7. *See* 16 C.F.R. § 801.10(b).
8. 16 C.F.R. § 801.1(a)(3) (Control is defined as either: 1) holding: a) 50 percent of the voting securities of a corporation, or b) in the case of an entity with no outstanding voting securities, having the right to 50 percent or more of the profits of the entity or having the right in the event of dissolution to 50 percent or more of the assets; or 2) having the contractual power to designate 50 percent or more of the board of directors. 16 C.F.R. § 801.1(b)).
9. The HSR filing fee is split into three tiers. Currently the fees, depending on the size of the transaction, are $45,000 (for transactions valued at more than $80.8 million but less than $161.5 million), $125,000 (for transactions valued at $161.5 million but less than $807.5 million), or $280,000 (for transactions valued at $807.5 million or more).
10. Note the agencies do not affirmatively approve any transaction.
11. The following link provides a sample second request that could be issued by the government. https://www.ftc.gov/enforcement/premerger-notification-program/hsr-resources.
12. Eric Kroh, Health, Pharma Sectors Will Be FTC Focus, Ohlhausen Says, *Law* 360, March 31, 2017, https://www.law360.com/articles/908609/health-pharma-sectors-will-be-ftc-focus-ohlhausen-says.
13. Press Release, Federal Trade Commission, FTC Approves Final Order with Parent Company of Bausch + Lomb (Feb. 8, 2017).
14. *Id.*