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Chapter 24

Licensing in the Pharmaceutical Industry:
Strategies and Questions Regarding
Antitrust Premerger Notification

Chapter 24

LICENSING IN THE PHARMACEUTICAL INDUSTRY: STRATEGIES AND QUESTIONS REGARDING ANTITRUST PREMERGER NOTIFICATION

Pioneer pharmaceutical manufacturers routinely collaborate with biotechnology research companies to develop and market new pharmaceutical products. These strategic alliances, which frequently involve IP licensing, help pioneer firms manage substantial R&D risks and assist biotechnology companies in bringing new products efficiently through the Food and Drug Administration (FDA) regulatory process to market. Such licensing has accelerated with the increasing costs of developing new drugs/biologics and the importance of adding biologics to pioneer pharmaceutical manufacturers' product portfolios. Further licensing increases in both volume and valuation should be expected due to the substantial additional expenditures on pharmaceuticals mandated by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003.¹

Under a long-standing informal interpretation of the Premerger Notification Office (PNO) of the Federal Trade Commission (FTC), an exclusive IP license is viewed as a transfer of assets; thus, it is potentially subject to the premerger reporting requirements of the Hart-Scott-Rodino Antitrust Improvements Act of 1976 (HSR Act), as amended.² The HSR Act requires parties to reportable acquisitions of voting securities or assets to file with both the Antitrust Division of the Department of Justice (DOJ) and the FTC, and to observe certain waiting periods before consummating the proposed transaction. The waiting period is intended to provide federal antitrust regulators with an opportunity to determine whether the proposed transaction may substantially reduce competition in violation of Section 7 of the Clayton Antitrust Act.³ If so, regulators may seek to enjoin the transaction from closing or seek some other remedy to cure the alleged harm to competition.

Determining whether the grant of a particular IP license will be subject to the HSR Act requires an understanding of a body of law and practice that is not always intuitive and that is still

1. Pub. L. No. 108-173, 117 Stat. 2066 (2003). For a discussion of this and other likely consequences of this legislation, see Stephen Paul Mahinka and Kathleen M. Sanzo, *New Medicare Act Provides New Competitive Landscape for the Pharmaceutical Industry*, FDLI Update, July/Aug. 2004, at 36.
2. 15 U.S.C. § 18a; ABA Antitrust Section, *Premerger Notification Practice Manual*, Interpretation No. 29 (3d ed. 2003) (hereinafter *ABA Manual*).
3. 15 U.S.C. § 18.

developing. This chapter provides general guidance with respect to the HSR Act implications of these licensing arrangements in the pharmaceutical industry context.⁴

Overview of the HSR Act

The HSR Act requires the ultimate parent entity of each party to a reportable transaction to file a Notification and Report Form with the FTC and the DOJ. In addition, the acquiring party must pay a filing fee.⁵ The transaction cannot be consummated until the expiration (or early termination) of the statutory waiting period—30 calendar days (15 days in the case of all-cash tender offers and bankruptcies).⁶ Before the expiration of the initial waiting period, the reviewing antitrust agency (either the FTC or the DOJ) may issue a request for additional information, which tolls the waiting period, thus prohibiting consummation of the transaction until 30 days (10 days in all-cash tender offers and bankruptcies) after satisfaction of the request.⁷ Upon the expiration of the relevant waiting period, if the reviewing antitrust agency believes that the proposed arrangement may harm competition, it may seek to enjoin the parties from closing the transaction or seek other conduct or structural remedy.

Size-of-Person and Size-of-Transaction Jurisdictional Tests

Regardless of the terms of any licensing arrangement, no HSR Act filing will be required unless two jurisdictional tests are satisfied: the size-of-person test⁸ and the size-of-transaction test.⁹

The size-of-person test inquires about the size of the ultimate parent entity of both parties to the transaction, together with all of the entities “controlled” by that ultimate parent.¹⁰ An entity controls a corporation if it holds 50% or more of the voting securities of that corporation or has the contractual right to designate 50% or more of the members of the corporation’s board of directors.¹¹ An entity controls a partnership or limited liability company if it has the right to 50% or more of the profits or 50% or more of the assets upon the dissolution of the business.¹² Generally, the size-of-person test is satisfied if one ultimate parent entity has \$119.6 million in annual net sales or total assets, and the other has \$12 million in annual net sales or total assets.¹³ Where the acquiring person has \$119.6 million in annual net sales and is not engaged in manufacturing, the size-of-person test is

4. The views of the PNO are subject to change; consequently, consultation with the PNO with respect to the terms of any particular licensing arrangement may be appropriate.

5. 16 C.F.R. § 803.9. The fee is \$45,000, \$125,000, or \$280,000, depending on the value of the transaction.

6. *Id.* § 803.10. If the end of any waiting period falls on a weekend or legal public holiday, the period is extended to the next business day. *Id.* § 803.10(b)(3).

7. *Id.* § 803.20.

8. 15 U.S.C. § 18a(a)(2).

9. *Id.*

10. 16 C.F.R. § 801.1(a)(3).

11. *Id.* § 801.1(b)(1)(i).

12. *Id.* § 801.1(b)(1)(ii).

13. 8 U.S.C. § 18a(a)(2)(B). Numeral thresholds for the size-of-person and the size-of-transaction tests are adjusted annually by the FTC based on the changes in gross national product, pursuant to Section 7A(a)(2) of the Clayton Act.

satisfied only where the acquired person has \$12 million in total assets.¹⁴ If the transaction is valued at more than \$239.2 million, the size-of-person test is eliminated.

The size-of-transaction test is met if the acquiring person acquires assets or voting securities of the acquired person that exceed \$59.8 million in value.¹⁵ Determining the HSR Act value for an IP license, in which substantial portions of the consideration may be contingent on future sales or other factors, is often complex.

When Is an IP License “Exclusive”?

In general, the PNO’s view is that the “exclusive” grant of a copyright, trademark, patent, know-how, or other technology license is regarded as the sale of an asset to the licensee if no other party—including the grantor—retains the right to use the IP.¹⁶ The grant of an exclusive license will be subject to the HSR Act’s reporting requirements if the jurisdictional thresholds are satisfied. A nonexclusive license, by contrast, is not a potentially reportable asset acquisition because the owner of the asset—the licensor—still enjoys some rights to the asset. Despite the seeming simplicity of the general rule, its application to pharmaceutical licenses exclusively for HSR Act purposes will depend on precisely what rights are being granted to the licensee and what rights are being retained by the licensor.

Field of Use and Geographic Territory

The PNO views exclusivity limited to a particular “field of use” or a partially exclusive license as exclusive for HSR Act purposes.¹⁷ For instance, the grant of an IP license for a pharmaceutical product used to treat a particular disease (e.g., diabetes) in the United States that transfers the rights to make, use, and sell the underlying compound or product will be an exclusive license for HSR Act purposes. Limiting the geographical territory or field of use affects the valuation of the “asset” being acquired but does not render the license nonexclusive.

March-in Rights or Termination Rights

March-in rights or termination rights under which the licensor retains the ability to assume the license rights if certain conditions are satisfied will not render a license nonexclusive for HSR Act purposes.¹⁸ Similarly, an exclusive IP license that is limited to a period of time (e.g., a license that expires five years after its execution) will still be exclusive, and thus potentially reportable, for HSR Act purposes.

14. *Id.*

15. *Id.* § 18a(a)(2)(A).

16. ABA Manual, *supra* note 2.

17. *Id.*

18. *Id.*

Transfer of Manufacturing Rights

The PNO takes the view that, if the licensee is not granted the right to manufacture the licensed pharmaceutical product, such license is not exclusive for HSR Act purposes.¹⁹ Instead, the FTC has concluded that such arrangement is analogous to a distribution agreement, which is not subject to the HSR Act because it does not involve the transfer of assets. Such license is considered nonexclusive, even if the licensor has no intent to manufacture the pharmaceutical product.²⁰

Active Pharmaceutical Ingredient vs. Secondary Manufacturing

Where a grantor retains the rights to manufacture the active pharmaceutical ingredient (API) but licenses the right to manufacture the finished pharmaceutical, the license is not considered exclusive.²¹

Combination Pharmaceutical Products

If the grantor licenses the right to use its compound in a combination drug product but otherwise maintains its IP rights and can therefore use that compound by itself, the license is not exclusive for HSR Act reporting purposes.²² Even if the grantor is prohibited from using the compound in another combination product, such license is not exclusive for HSR Act purposes, despite the potential substantive antitrust issues raised by such restriction.²³

Co-Marketing, Co-Development, and Profit-Sharing

If the grantor licenses all of its IP rights for a product, retaining only the right to co-market or co-promote the product (e.g., through its own sales force), the license is considered an exclusive license for HSR Act purposes, and thus is reportable.²⁴ Similarly, the PNO views an agreement to share profits as indistinguishable from a royalty arrangement; consequently, such an agreement would not exempt an otherwise reportable exclusive license from the HSR Act.²⁵ The grant of a distribution right alone—even if on an exclusive basis—does not constitute an exclusive license for HSR Act purposes.²⁶ Retaining the right to fund the development of a product candidate is insufficient to render the license nonexclusive.²⁷

Where Manufacturing Rights Are Transferred Subsequent to the Original Closing

Where a licensor retains the right to manufacture a product for a period of years—usually until certain royalty payments are made or clinical trials have ended—such a license is considered nonexclusive, but will become exclusive when the manufacturing rights are transferred to the

19. Morgan, Lewis & Bockius LLP (Morgan Lewis) teleconferences with the PNO (Aug. 1, 2001 & Mar. 3, 2002).

20. Morgan Lewis teleconference with the PNO (Dec. 15, 2003).

21. Morgan Lewis email exchange with the PNO (Feb. 17, 2004).

22. Morgan Lewis teleconference with the PNO (Dec. 3, 2001).

23. *Id.*

24. Morgan Lewis teleconference with the PNO (Mar. 6, 2002).

25. *Id.*

26. *Id.*

27. *Id.*

licensee. Assuming that the size-of-person and size-of-transaction tests are satisfied and that no exemption applies, the parties must make HSR Act filings and observe the relevant waiting period before the manufacturing rights can be transferred to the licensee.

Under the HSR Act rules, a transaction must be consummated within one year after expiration of the relevant HSR Act waiting period to benefit from the clearance.²⁸ If the closing has not taken place within that time, the parties must file again under the HSR Act. Depending on when the manufacturing rights will be transferred, the parties may have to wait to file until long after the underlying licensing agreement is executed. The potential exists, therefore, for the FTC to unwind a transaction as a result of its HSR Act review if it concludes there is a violation of Section 7 of the Clayton Act. One way to avoid this unsatisfactory result would be for the parties to license the manufacturing rights up front (thus subjecting the license to HSR Act review), but then to sublicense the manufacturing rights back to the original licensor on a nonexclusive basis and pursuant to a separate agreement.

Co-Exclusive License Grant to Two Licensees

Another way in which a biotechnology company can reduce its development risks is to license the IP relating to a product candidate to two pharmaceutical companies with complementary capabilities. The FTC takes the position that such co-exclusive arrangements are not exclusive for HSR Act purposes, even if the licensor grants the rights to make, use, and sell the pharmaceutical product candidate to the two licensees and retains no rights itself.²⁹

Valuation of an Exclusive License

The licensee as the “acquiring person” must value an exclusive license to determine whether the size-of-transaction test is satisfied and to determine the appropriate filing fee. The size-of-transaction jurisdictional test is satisfied if the value of the license exceeds \$59.8 million.³⁰ Valuation of an exclusive license in the pharmaceutical industry presents a host of complexities. For instance, even for candidates licensed while in Phase 3 clinical trials, there remains some chance that the candidate will not receive FDA approval. This uncertainty is a larger factor for candidates licensed in Phase 2 or earlier in the FDA regulatory approval process.

Exacerbating the historic uncertainties of whether and when FDA approval will be obtained are the additional questions as to likely reimbursement levels raised by changes mandated by the Medicare Act. The change to an average sales price (ASP) system, the development of therapeutic reimbursement categories through the U.S. Pharmacopoeia, and the potential development of administrative cost control mechanisms by the Centers for Medicare and Medicaid Services all create significant difficulties in reasonable valuations of candidate products.³¹

28. 16 C.F.R. § 803.7.

29. Morgan Lewis teleconference with the PNO (Jan. 27, 2003).

30. 18 U.S.C. § 18a(a)(2)(A).

31. See Mahinka and Sanzo, *supra* note 1, at 38.

Under the HSR Act regulations, the acquiring person is required to value the assets for purposes of the size-of-transaction jurisdictional test within 60 days prior to closing or the filing of a premerger Notification and Report Form pursuant to the HSR Act.³² In an asset sale, the value of the transaction is the greater of the asset's fair market value (FMV) or its acquisition price.³³ The acquisition price is the total amount of consideration received by the seller for the acquisition of its assets.³⁴ That consideration includes the value of any accrued liabilities assumed by the acquiring person, and any separate amount paid to the seller for a covenant not to compete.³⁵ The acquisition price is "determined" if the parties have agreed upon the consideration, or if the amount of consideration (by reason of postclosing adjustments or contingent future payments) can be reasonably estimated.³⁶ The PNO suggests, for example, that where earnouts are based on an evaluation of historical sales growth, a reasonable estimate may be possible, although such estimates are impossible for products still in the approval process. The PNO also has noted that milestone payments keyed to approval from FDA may be too speculative to allow for a reasonable estimate. Anticipated future payments that can be reasonably estimated are included at face value and cannot be discounted to present value.

If the acquisition price cannot be determined because it is not possible to reasonably estimate whether certain future contingent payments will be achieved because of the number of uncertain risk factors, the FMV governs the value of the transaction. Under the HSR Act rules, the board of directors of the acquiring person or its designee is responsible for calculating the FMV of the assets. To calculate the FMV, any genuine methodology used in good faith that is not designed to avoid an HSR Act filing is appropriate. Indeed, the FTC has indicated that the most appropriate formulation of the FMV would be to determine how much the buyer would pay at present in cash for the assets being acquired, without the contingent payments.

Ultimately, the pioneer manufacturer licensee (the acquiring person) must determine whether a reasonable estimate of the value of contingent payments is impossible—in view of the quality and quantity of the risk factors associated with bringing the underlying product to market, its stage in the approval process, and its likely sales volume and level of reimbursement.³⁷ If so, the acquisition price cannot be determined, and an FMV may be used. Often, the only certain compensation is the up-front cash payment because all other payments are conditioned on events that may not happen. Under those circumstances, as long as the FMV and the known consideration for the assets do not exceed \$59.8 million, no filing is required. Because the acquiring person is responsible for valuing the license, if no filing will be made, it is customary for the licensor to request a representation from

32. 16 C.F.R. § 801.10. Terms capitalized herein are defined in the HSR Act and rules.

33. *Id.*

34. *Id.*

35. ABA Manual, *supra* note 2, No. 32 (treatment of noncompetes) and No. 122 (treatment of liabilities in valuing assets).

36. *Id.* No. 101 and No. 107.

37. *Id.* No. 91 and No. 101.

the licensee to the effect that it has discharged its obligations under the HSR Act rules and has determined that no HSR Act filing is needed because the size-of-transaction test is not satisfied.

Acquisition of Foreign Assets

If the size-of-transaction jurisdictional threshold is satisfied, the parties should assess whether an exemption may apply. For example, pursuant to Rule 802.50, the acquisition of foreign assets is exempt if the sales generated from those assets do not exceed \$59.8 million.³⁸ If, as is ordinarily the case, no sales are yet attributable to the exclusively licensed IP, the acquiring person may subtract from the valuation of an exclusive license the value of the non-U.S. rights. In so doing, if the nonexempt value does not exceed \$59.8 million, no HSR Act filing will be required.

Investment-Only Exemption

Pioneer pharmaceutical manufacturers commonly finance the development efforts of biotechnology companies by acquiring an equity interest in them. Under the investment-only exemption of the HSR Act rules,³⁹ an acquisition of voting securities is exempt from the reporting obligations of the HSR Act whenever:

- As a result of the acquisition, the acquiring person will hold 10% or less of the outstanding voting securities of the issuer
- The acquisition is made solely for the purpose of investment
- The issuer is not a competitor of the acquired person or any entity it controls

An acquisition is made solely for the purpose of investment when the acquiring person has “no intent in participating in the formulation, determination, or direction of the basic business decisions” of the issuer whose shares are being acquired.⁴⁰ The FTC takes the position that an acquisition of voting securities is made solely for the purpose of investment only when the acquiring person intends to take a completely passive role with respect to the issuer whose voting securities are being acquired. This generally means that the acquiring person has no intention of attempting to influence the management of the issuer whose shares are being acquired regardless of that issuer’s financial performance, strategic plans, and decisions. The FTC has determined that the investment-only exemption does not apply if an acquiring person will sit on the board of the acquired issuer or will place an employee as an officer of the acquired issuer. In addition, if the acquiring person is a competitor of the acquired person, the investment-only exemption is unavailable. The PNO is of the view that pharmaceutical companies are not competitors for HSR Act purposes unless they have actual or potential competing products or product candidates.⁴¹

38. 16 C.F.R. § 802.50.

39. *Id.* § 801.1(i)(1).

40. *Id.* See *United States v. Smithfield, Inc.*, Civ. Action No: 1:03CV-434 (Mar. 28, 2003) (alleging that the investment-only exemption was not available to Smithfield in connection with its acquisitions of shares of rival IBP, Inc. because Smithfield was contemplating a merger with IBP at the time it made its acquisitions of IBP shares).

41. Morgan Lewis teleconference with the PNO (Apr. 11, 2002).

Conclusion

Application of the HSR Act to pharmaceutical licensing arrangements presents a number of complexities, which are enhanced by the new Medicare Act. Pioneer pharmaceutical manufacturers and biotechnology companies thus should carefully assess their strategies regarding the HSR Act reporting obligation and the structuring of their IP licenses.