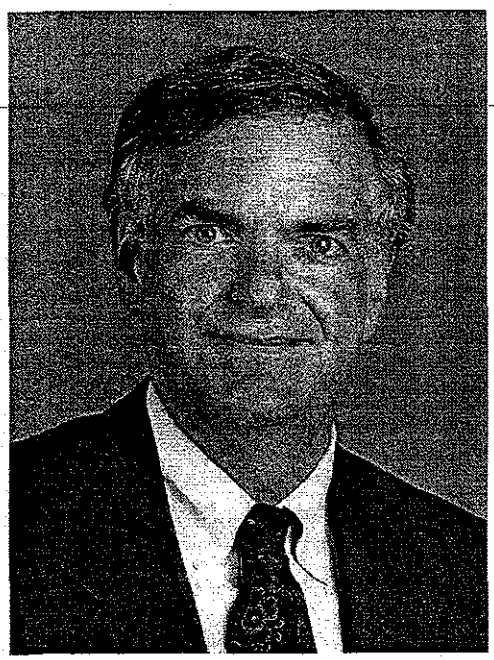


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BIOTECH LICENSING

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A. AVAILABLE OPTIONS

A license is a grant by one party (the "Licensor") to another party (the "Licensee") to use the first party's intellectual property, or, in some cases, tangible property. Licensing transactions can be simple, or they can be complex. They can range from a simple exchange of a lump-sum cash payment for a fully paid, perpetual, worldwide, nonexclusive license to practice the inventions claimed in a patent without any transfer of know-how or tangible materials and without representations or warranties as to validity by the patentee, to a collaborative research arrangement in which two parties perform research and cross-license the results to each other for specified territories or fields of use, to turnkey construction of a fermentation facility ready to produce a protein product at commercial scale, together with a license to use all present and future relevant patents and know-how of the Licensor. The first case involves very few complex issues and almost no ongoing relationship, while the two latter cases will require a very careful definition of each aspect of the relationship, since it will be an ongoing interactive relationship for a number of years. In each case, however, all available options should be considered.

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1. Subject Matter of License

The intellectual property to be licensed consists of patents, trademarks, service marks, tradenames, copyrights (and/or applications therefor), trade secrets and know-how (accumulated skills, experience, processes and procedures not reaching the level of trade secrets). The various types of intellectual property constituting possible subjects of a license agreement have different attributes and are differently protected, some by statute and some by common law.

While any tangible property can theoretically be licensed, for most types of technology other forms of conveyance of a "right to use" are employed, such as a sale or lease. However, in biotechnology, new types of "tangible" property, consisting of biological materials such as DNA, RNA, cell lines, vectors, plasmids, hybridomas, monoclonal antibodies, and modified organisms are the subject of licenses. Even in these cases, the value of the tangible object is its physical embodiment of intellectual property. In licensing such property, while the legal considerations are basically the same as with "pure" intellectual property, special considerations arise as a result of the "living" nature of the property. A license must deal not only with the right to use the property delivered, but also with ownership of, and the right to use, its progeny, derivatives, mutants and products. Unlike licenses of "pure" intellectual property, where there is a long history of commercial behavior and case law to define relative rights of the parties in the absence of a clear agreement, the biotechnology industry is only twenty-five years old, there is still very little law directly on point. Therefore, it is important that a license agreement covering biological materials deal not only with the materials delivered by the Licensor, but also with the use of progeny, derivatives, mutants, products and the like, including ways to determine whether a biological material different from the one initially delivered is, in fact, such a material. So long

as the parties stay within the legal constraints discussed below, they should be free to reach any agreement which suits their commercial purposes.

2. Make, Use, Sell and Import

The grant of a patent gives the owner of the patent the exclusive right to make, use, sell, and import products embodying or made with the practice of the subject of the patent (35 U.S.C. Sec. 154). This four part right to make, use, sell, and import forms the first option for defining the rights of the Licensee to intellectual property. A license may grant rights to one or more of the four categories, and the decision of the parties should be clearly spelled out. For example, a license for internal use of a research tool would grant rights to make and use, but not to sell or import. A license to a manufacturer who will make and market a reagent kit, but who is not authorized to operate a service business with the reagents will grant rights to make, sell and import, but not to use.

3. Field of Use Restrictions

A license restricted by "field of use" grants the Licensee the right to use the licensed intellectual or tangible property for only limited applications, and not in every possible way. While there are some arguments to the contrary, it is generally agreed that field of use restrictions in license agreements are permissible as to all areas of intellectual property. See, e.g., General Talking Pictures Corp. v. Western Electric Co., 305 U.S. 124 (1938); Bela Seating Co. v. Poloron Products, Inc., 438 F.2d 733 (7th Cir. 1971); Benge Laboratories, Ltd., v. R. K. Laros Co., 209 F.Supp. 639 (E. Pa. 1962), aff'd per curiam 317 F.2d 455 (3d Cir. 1963), cert. denied 375 U.S. 833 (1963); U.S. v. Ceiba-Geigy Corp., (1976-1) Trade Cas. Para. 60,908 (D. N.J. 1976).

The concept of field of use licensing is best illustrated by example. If the subject of a license is a patent on a new method of inserting plasmids into bacteria, the patent owner could license one Licensee for use to produce human pharmaceuticals and another for use to produce organic chemicals. Each of these limited applications would be a field of use. In biotechnology, special care should be given to consideration of field of use restrictions. Many inventions will have use in both therapeutics and diagnostics. Some inventions will have applications in fields that are not anticipated when the license is negotiated. Even the "usual" fields must be carefully considered. For example, does a license in the field of "vaccines" include the new "cancer vaccines" being developed? These are therapeutic products, not prophylactic products, but they operate by stimulating the immune system in the same way as traditional prophylactic vaccines. Does the right to use a gene to "genotype" a patient fall under the "diagnostic" field? Does it matter if the genotyping is for the purpose of determining whether a specific therapeutic should be administered? Because biotechnology is evolving so quickly, either the Licensee or the Licensor should have the right for all unidentified fields so that no area is left out of the rights. For example, an agreement should not give diagnostic rights to Licensee and therapeutic rights to Licensor. Instead, Licensor should retain rights in "all fields other than diagnostics." An additional problem arises with field of use questions in pharmaceutical products. Since these products are subject to strict regulation, an adverse event by one licensee in its field of use can impact another licensee that is developing the same compound in a different field. Also, if a field of use division of rights is based on the indication for which a therapeutic product is to be sold, the parties must address the issue of "off-label" use. For these reasons, licensees in the pharmaceutical industry often insist on having rights in all fields, even if they do not plan to

exploit all fields, or at least insist that licensees in other fields be required to use a different formulation of a licensed compound.

4. Exclusivity

There are three common degrees of exclusivity granted in licensing transactions, exclusive licenses, sole licenses and nonexclusive licenses.

Exclusive License - gives the Licensee the right to use the licensed intellectual or tangible property and the right to exclude all others, including the Licensor, from use thereof.

Sole License - gives the Licensee the right to use the licensed intellectual or tangible property, subject to a retained right in favor of the Licensor, and the right to exclude all persons other than the Licensor from the use thereof.

Nonexclusive License - gives the Licensee the right to use the licensed intellectual or tangible property but no right or say as to its use by others.

(Note: a common error in license agreements is the grant of a "sole and exclusive license." This language can create ambiguity and should be avoided).

In biotechnology, licenses for therapeutic or diagnostic products are generally exclusive, at least for a field of use and a territory, while licenses for "tools" and databases are generally nonexclusive. Licenses for drug targets vary, depending on the structure of the overall relationship providing access to the target. For example, licenses to targets found in a database to which the licensee subscribes will generally be nonexclusive, while licenses to a target discovered in a research collaboration will generally be exclusive.

5. Sublicense Rights

The license agreement should expressly state whether and to what extent the Licensee may grant sublicenses, or, in the case of biological materials, deliver those materials and the right to use them to others. The right, if granted at all, can be as broad as the basic license or can be limited to various subcategories by "make, use, sell or import," by territory, by field of use or by type of sublicensee. Care should be taken, however, to be sure that either the Licensee or the Licensor has the right to grant further licenses without consulting with the other to avoid antitrust complications see e.g., U.S. v. Besser Mfg. Co., 96 F.Supp. 304 (E.D. Mich. 1951) and "Letter from Department of Justice to Salk Institute dated December 16, 1975," Patent, Trademark and Copyright Journal, January 8, 1976 at A-4). Care should also be taken to define clearly the royalty rights of the Licensor with respect to sublicenses, as discussed below.

6. Territorial Restrictions

A patent monopoly granted to a U.S. patent holder gives it the right to grant geographically limited licenses, and thus, where just patents are involved, geographic market restrictions are permissible. (See 35 U.S.C. 261, and, e.g., Brownell v. Ketchum Wire and Mfg. Co., 211 F.2d 121 (9th Cir. 1954). In addition, since patents are granted on a country-by-country basis, territorial restrictions can be achieved by the use of grants of licenses only under particular patents issued by particular countries. Care must be taken, however, to comply with Articles 85 and 86 of the Treaty of Rome and the numerous regulations thereunder where EEC countries are involved. In addition, care must be taken not to attempt to restrict the activities of a patent licensee in countries where no patent protection exists, since this may be held to be an illegal attempt to extend the patent monopoly and therefore to be "patent misuse."

While there is little or no statutory authority for territorially restricted licenses to trade secrets and know-how, it is generally believed that such restrictions are valid, unless they are a subterfuge for a market division scheme. A territorially restricted license to manufacture must, however, be distinguished from territorial restrictions on resale of patented products, which may be an antitrust violation.

7. Improvements and Grantbacks

A license can cover the intellectual property as it exists at the time of the agreement, but it can also contain rights to advances or improvements made by the Licensor. Careful definition of what constitutes a licensed improvement is required, since the parties are dealing with unknown intellectual property and since the continuation and amount of royalty payments may depend on it. Similarly, where patent applications or patents are licensed, the agreement should clearly indicate whether continuations-in-part and foreign equivalents are included.

The license can also require that the Licensee grant rights to the Licensor with respect to advances and improvements made by the Licensee. If such "grantbacks" are included, they should be viewed as a separate license and all elements should be considered. Also, grantbacks raise potential antitrust and patent misuse problems which should be carefully considered, especially under applicable EEC regulations. With biological materials, careful consideration of these issues as they pertain to derivatives, progeny and mutations can be particularly important.

B. ELEMENTS OF A LICENSE AGREEMENT

1. Warranties And Covenants

a. Confidentiality

A potential Licensor generally requires a confidentiality agreement from the potential Licensee before "showing" the technology (not necessary for copyrights, trademarks and patents which are disclosed as a condition of statutory protection). Once a license agreement is signed, confidentiality is generally required by both parties. In cases of exclusive licenses, consideration should be given to whether confidential information initially belonging to Licensor should be treated as confidential information of Licensee, since the commercial value of that information now belongs to Licensee.

Standard exceptions to the confidentiality obligation are:

- information which at the time of disclosure is (or thereafter becomes through no fault of disclosee) part of the public domain;

- information which at the time of disclosure is already in the possession of the disclosee;

- information later received by the disclosee from a third party having the right to disclose it; and

- information required by law to be disclosed.

In addition, many recipients of confidential information, especially large companies with multiple research operations, insist on an exception for information "independently developed"

by the disclosee. If such an exception is included, it should be limited to "independent development by persons having no access to the confidential information."

The time period for the confidentiality obligation should be express. If the technology will not become public via "reverse engineering" of products after sale, a long time period of protection is necessary and appropriate. If the principal protection will be via patents, the time period should be long enough to cover expected prosecution of patent applications. In negotiating confidentiality clauses where patent applications will be filed, one should consider the impact on confidentiality of foreign patent applications, since many countries publish a patent application eighteen months after the claimed priority date.

Before signing a confidentiality undertaking, a Licensee should try to determine how closely the technology relates to internal R & D activities and should not accept in confidence technology which Licensee expects will fall under the exception for information already in its possession. The Licensee should also determine whether existing internal procedures will protect received technology or whether special handling or special limitations on internal access will be required to insure compliance with its non-disclosure agreement.

The biotechnology industry has developed a special problem in the area of confidentiality. Because many researchers in biotechnology companies have academic backgrounds, and because biotechnology companies use publicity about discoveries and early developments to enhance their stock values in the public and private equity markets, many discoveries by biotechnology companies are published in scientific journals in a manner that is not the norm for bigger companies. This issue must be carefully dealt with by a license agreement to assure that publication does not adversely affect patentability.

b. Ownership

Licensor generally warrants ownership of the intellectual property which is the subject of license and the right to grant the license. Note that, in the case of jointly owned patents, there is a difference between U.S. law and other jurisdictions. In the U.S., any owner of a joint interest in a patent may grant a license, while in Europe, a valid license can only be granted with the consent of all joint owners.

c. Validity

Licensor generally does not warrant patent validity, but frequently does warrant good faith, non-fraudulent prosecution of the patent application and may warrant absence of knowledge of any claim of invalidity.

d. Non-Infringement

Licensor sometime warrants that practice of the licensed intellectual property does not infringe rights of third parties. This is much less common in the biotechnology area where licenses are frequently granted at an early stage before any patents are issued, and where many key inventions are in competitive areas in which many companies are pursuing the same research. In these cases, it is not possible to determine infringement with any degree of certainty for many years until all applications are published and interferences resolved. Licensor frequently warrants that the practice of the licensed intellectual property does not infringe any other rights of Licensor.

e. Implied Warranties

There may be an implied warranty by licensor akin to a warranty of fitness for a particular purpose under the UCC. Unless Licensor is prepared to make such a warranty, this should be negated.

f. Licensee Performance/Diligence

Licensee generally gives some covenant with respect to its efforts to exploit the licensed intellectual property. This is often the subject of difficult negotiations because of the long product development cycle in biotechnology products and the possibility that the Licensee's priorities or the relevant market will change dramatically. The most common standard is "commercially reasonable efforts consistent with the level of effort Licensee expends on other products of similar commercial potential." If the Licensor wants to be certain the technology is developed, however, a more objective measure of diligence will be required. Some examples are:

- time limits to reach milestones ("file an IND by December 31, 2001")
- committed expenditures ("spend at least $5,000,000 per year on clinical trials")
- minimum royalties or annual license maintenance fees.

2. Royalties

Royalties can consist of a combination of elements, and they should all be considered as part of a package in negotiating a license agreement. The basic elements consist of initial or "up front" payments (which can be made both before the license is negotiated as a good faith payment for "peeking into the black box of the technology" or upon execution of the agreement), compensation for services rendered, minimum and/or maximum royalties and earned royalties.

In each case, it is very important to review the impact of the patent and intellectual property laws and the antitrust laws on the available alternatives in the overall package under the given set of circumstances.

a. Earned Royalty

The most common element of any royalty package is the so-called earned royalty, which relates royalty payments directly to use of the technology. Earned royalties are paid on a formula basis (royalty base multiplied by royalty rate for a period of time).

Royalty Base - The royalty base is that element on which the royalties are going to be paid. The royalty base should be capable of administration without dispute to the extent possible. For example, it can be the number of units manufactured, the number of units sold, the cost of manufacture, sales price of units sold, the number of iterations of a given machine practicing a process patent, or any other formula that is reasonably designed to relate the payment of royalty to the actual use of the licensed intellectual property by the Licensee. In cases where the licensed invention improves an already existing product (for example, in agricultural biotechnology where an improved trait is added to an existing seed line), the royalty base sometimes consists of "value added," measured by the difference in price between the improved and unimproved product. This is obviously difficult to administer and does not take into account increased volume as a result of the improvement or simply retaining market share that would be lost without the improvement. A simpler and easier model would be a lower royalty rate on the entire price of the product, rather than a higher rate on only a part of the price. It is not appropriate, and may in fact be "patent misuse," to use as a royalty base the total output or total sales of the Licensee, unless that total output and total sales depend upon the use of the intellectual property licensed. (See Zenith Radio Corp. v. Hazeltine Research, Inc., 395 U.S. 100

(1969)). Use of "profits" as a royalty base often leads to disputes and should be avoided since the calculation of profit on a particular product requires a number of subjective judgments to allocate selling, overhead and other costs.

- Assuming the use of the most typical royalty base, a revenue from product sales, the agreement should specify how the royalty base is determined. Usually, a "Net Sales" concept is employed, allowing deduction from gross revenues of various costs, such as shipping, sales taxes and returns. The royalty provisions should also specify whether products sold through affiliates or sublicensees of Licensee will bear the same royalty as direct sales by Licensee or whether payments by the sublicensee to the Licensee will be divided. In many cases, particularly for drug products, a proration formula for combination products and an allocation method for bundled products should be included. Finally, careful consideration must be given to how the product will actually be sold. For example, if a drug is delivered as part of a therapeutic procedure in which the same entity provides both the drug and the procedure for a single price, the royalty should be based on the total price or a means of allocating the price between the product and the service must be agreed upon.

Royalty Rate - The royalty rate will consist of a dollar amount or a percentage, depending on the royalty base. The royalty rate can vary with time or with volume. For example, the royalty rate could be four percent of sales during the first year to allow Licensee a start up period and five percent thereafter; or it could be seven percent on the first $100,000,000 of sales, eight percent on the next $100,000,000 and ten percent thereafter, either annually or cumulatively. The theoretical range in which a fair royalty rate should fall is between a minimum equal to the lowest acceptable return to the Licensor and a maximum equal to the cost of the next best

alternative to the Licensee. Between these two points, various factors should be considered to fix an appropriate royalty rate. These factors include:

- royalty rates previously used by the Licensor or paid by the Licensee in similar transactions with arm's-length third parties. These data can serve as guidance in establishing the royalty rate in a given transaction, but should not be used automatically by rote to set royalties in another transaction, since only rarely are two transactions identical.

- prevailing royalty rates in the industry.

- savings or profits to the Licensee from the transaction. A commonly used rule of thumb is that 25 percent to 33 percent of pretax profits or savings to the Licensee from the license constitutes a fair royalty. However, this "rate" should not be used as the royalty formula -- instead it should be translated into a percentage of sales.

- Licensee's gross margin (revenue less cost of sales, before selling and general and administrative expenses) on the product in question. This is an easier number to look at than savings or profits, since there are fewer subject allocation questions.

Royalty Reductions - Where additional technology will be required in order to practice the licensed technology, provision should be made for sharing the cost of royalties paid for the additional technology. For example, licensee may be permitted to deduct third party royalties (or a portion thereof) from royalties payable to Licensor, with a limit on the extent to which the offset can reduce the amount payable to Licensor. If such a provision is included, the third party royalties which are permitted to be offset must be carefully defined.

Royalty Period - The royalty period depends on the subject of the license. Royalties for patents, copyrights and trademarks cannot go beyond the life thereof, by expiration or invalidation (see Brulotte v. Thys Co., 379 U.S. 29 (1964), rehearing denied, 379 U.S. 825 (1950)). Royalties for trade secrets or know-how can be perpetual, if the parties so agree, but are frequently limited either to a fixed period or set to terminate when the licensed property becomes part of the public domain (see, however, Aronson v. Quick-Point Pencil Co., 440 U.S. 257 (1979).

Since royalties on patents cannot extend beyond the life of the patent, where both patents and know-how are licensed, it is wise to separate the royalties payable with respect to each so that later invalidation of the patent will not result in total termination of royalties. Also, provision is sometimes made for a decrease in royalties on products covered by multiple patents as the patents expire or become invalid. See e.g., Beckman Instruments v. Tech Development Corp., 433 F.2d 55 (7th Cir. 1979)). Notwithstanding these legal concepts, biotechnology royalties are sometimes not bifurcated between patent royalties and know-how royalties on the basis that it is a combination of Licensor's know-how and patents that generated the licensed product. Where there is a distinction in royalties between patented and unpatented products, a frequent issue is which rate to apply to products within the claims of pending but unissued patent applications. The Licensee wants them treated as "unpatented" to prevent the Licensor from collecting higher royalties while a patent sits in the patent office forever, while the Licensor argues that its patent is valid and will surely issue in due course. A reasonable solution is to pay the higher royalty if the product is covered by an application that has been pending in less than a fixed number of years (the number should depend on norms for the industry and country), but to

ignore the pending application if it has not been issued after that period unless and until a patent finally issues.

b. Minimum Royalties

Minimum royalties are fixed amounts required to be paid by the Licensee regardless of the level of use of the technology or earned royalties due. They are used for several reasons, including:

- To establish a minimum return to the Licensor, helping it recover the cost of developing the technology and making sure that it does not suffer a loss.

- To assure diligence by the Licensee in its exploitation of the license, the theory being that if the Licensee is required to pay significant minimum royalties regardless of sales, it will be diligent in attempting to achieve sales.

A true minimum royalty is an amount payable as a contractual obligation regardless of whether any sales are made or any earned royalties accrue. An alternative use of minimum royalties is to provide a test for maintenance of the license or its exclusivity. Particularly where there are numerous products on which royalties are paid and it is difficult to establish a sales test to determine whether sufficient products have been sold to warrant the maintenance of the license either in general or as an exclusive license, the actual royalties paid during the year can be reviewed and if they did not achieve a given level, then additional payments can be made at the Licensee's option to maintain exclusivity or the existence of the license.

c. Initial or "Up-Front" Payments

Initial or "up-front" payments are generally required to compensate Licensor for the cost of developing the licensed technology, to establish the good faith of the Licensee, or to establish a minimum return for the Licensor where no significant annual minimum royalties are due.

d. Milestone Payments

Milestone payments (amounts to be paid on achievement of specific events) are used to compensate Licensor for increasing value of the technology as it progresses toward commercialization or to provide cash flow to Licensor during the period between the grant of the license and the commencement of royalties when the licensed product is introduced to the market. Milestone payments are sometimes credited against future royalties. Milestone payments can be especially important in biotechnology because of very long product development times.

e. Compensation for Services

If a license calls for training of the Licensee's personnel, set up of Licensee's facilities, delivery of the licensed technology in a specific form, or further development of the licensed technology by Licensor, part of Licensor's compensation can be payments for services, measured by the man-hours involved.

f. Other Forms of Compensation

Other forms of compensation are available, such as cross licenses to the Licensee's intellectual property, a grantback of rights to improvements made by the Licensee, or even an equity interest in Licensee's business.

3. Infringement Of Licensed Rights By Third Parties

A license agreement should deal expressly with the rights and obligations of the parties in the event of the unlicensed practice of the licensed rights by a third party.

In the case of know-how or trade secrets, there is no remedy unless they have been "stolen" by the third party, although the agreement could provide for reduced royalties.

For patents, trademarks and copyrights, the "infringement" can be stopped through litigation. For exclusive licenses, agreements generally provide protection against infringers at Licensor's expense. For nonexclusive licenses, protection is generally not provided.

The agreement should spell out:

- the method to determine when "infringement" has occurred.

- the extent of the obligation of the Licensor to cause it to cease and the time period for such action.

- the consequences of the infringement and Licensor's failure to cause it to cease (e.g., giving Licensee the right to pursue the infringer, suspension of royalties, or both).

- who bears the cost of obtaining cessation and who gets the benefit of any recovery against the infringer.

4. Audit Rights

The agreement should provide the Licensor with the right to audit the books of the Licensee (and its sublicensees) to determine if proper payments have been made. Generally, the audit must be done by an independent auditor within a limited time period (often 3 years) after

the royalty period in question. Generally, the licensor pays for the audit unless a significant (2-5%) error is found, in which event the Licensee pays for the audit.

5. Expiration And Earlier Terminations

A license of intellectual property with a statutory term cannot exceed life thereof (e.g., a license to U.S. patent cannot exceed 17 years from date of issuance for a pre-GATT patent and 20 years from the priority date for the application in the case of a post-GATT patent, subject to patent term extension. A license of trade secrets or know-how can be perpetual.

A license agreement should provide for early termination.

- By Licensee, in the event Licensee no longer wants the license, often upon payment of a "liquidated damage" amount where minimum royalties are involved.

- By Licensee, upon patent invalidity.

- By Licensor, upon breach by Licensee.

Termination provisions should deal with:

- Rights of both parties to use the licensed intellectual property after termination.

- Return of written or physical embodiments of licensed property where Licensee is no longer authorized to use the licensed property.

- Return or destruction of biological materials and their derivatives, progeny and mutations.

- Liquidation of inventory of products made with licensed property on hand at time of termination.

- Grant by Licensee to Licensor of rights to improvements and, in some cases, rights to take over regulatory filings with respect to licensed products.

C. OTHER ISSUES

1. Hart-Scott-Rodino

Although a license agreement is not an acquisition, the Hart-Scott-Rodino Antitrust Improvement Act of 1976 (15 U.S.C. §18a) still applies. The Hart-Scott-Rodino Act requires that a notification be filed with the Federal Trade Commission and Department of Justice with respect to any transaction involving an acquisition of assets or stock of one party by another if the transaction meets the "size of parties" and "size of transaction" tests. The size of parties test is met if one of the parties to the transaction (or the "ultimate controlling person" of a party) has $100,000,000 of assets or annual revenues and the other party (or its ultimate controlling person) has $10,000,000 of assets or annual revenues. The size of transaction test is met if the value of the transaction exceeds $15,000,000.

The Act is clearly triggered by the transfer of voting securities or tangible assets, but may less obviously apply to the grant of a license. However, the Federal Trade Commission has taken the position that the grant of an exclusive license constitutes a transfer of property for purposes of the Hart-Scott-Rodino Act, and therefore requires an analysis of the Act's filing thresholds. *See* Memorandum to file from F.T.C. attorney Dana Abrahamsen dated July 19, 1982, *reprinted in* Bruce S. Prager ed., *Premerger Notification Prac. Manual*, 1991 A.B.A. Sec. Antitrust L. Rep.

It is the responsibility of both parties to determine whether the value of an exclusive license meets the size of transaction test in order to satisfy their Hart-Scott-Rodino filing

obligations. A good faith determination by the Company or its Board of Directors, based on factual information, will suffice. In determining the value of an exclusive license, upfront payments generally are counted, but royalties generally are not counted since they are uncertain, even where the product already exists, unless the level of sales (or a minimum level of sales) can be determined with reasonable certainty. The more difficult question is the value of minimum royalty obligations and milestone payments. These amounts may or may not be counted, depending on the certainty of achieving them. *See* 16 C.F.R. §§ 801.10(b), (c) (1998).

If the tests are met, both parties are required to notify the Federal Trade Commission and Department of Justice of the transaction by completing a Notification and Report Form. A thirty-day notice period then follows, during which the parties may not proceed with the transaction, unless early termination of the waiting period is granted. The FTC or Antitrust Division may request additional information, which can further delay the consummation of the transaction. Ultimately, if the FTC or the Antitrust Division objects to the transaction, it may initiate an antitrust challenge to the transaction. It is also possible, in a multi-step transaction, that no filing would be required at the initiation of the transaction, but may be required at a later stage when equity is purchased, assets are transferred, or an exclusive license is granted.