

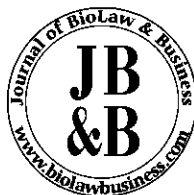
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Collaborative Agreements in Biotechnology: Issues in Global Negotiations from the U.S. Perspective

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ABSTRACT

This article reviews the specific issues of patent misuse, a licensee's right to challenge patent validity, distinctions in United States (U.S.) federal and state law, considerations of jointly owned patents and antitrust concerns in the context of international collaborations wherein there are issues of U.S. law.

NEGOTIATING BIOTECHNOLOGY COLLABORATIVE AGREEMENTS THE INTERNATIONAL CONTEXT

Most science today is global. Scientists on one side of the globe seek out others all over the world for research collaborations. The agreements are rarely only national and usually patents are involved. Accordingly, collaborative research and development agreements ("CRADAs") must be viewed in an international context. Nevertheless, many of the issues are subject to local law and regulation. The major markets are North America, Europe and Japan. All three of these markets are different and inconsistent insofar as their treatment of issues such as patent, regulatory, medical, pricing (Europe and Japan) and health care reimbursement. There are specific nuances that are both countrywide as well as local.¹

Transactions within the biotech industry are becoming larger, more complex and different. Large pharmaceutical companies and biotech companies are jointly developing products together, and biotech companies are engaging in collaborations in the ever-growing fields of genomics, bioinformatics and e-health. There is a growing emphasis on software and data services in genomics and bioinformatics, and these transactions, like others within the biotech field, are not merely local but international.

BIOTECH DEALS ARE LARGER AND MORE COMPLEX ON BOTH SIDES OF THE ATLANTIC

GROWTH OF THE U.S. SECTOR

To further appreciate the place of CRADA's and their use and growth worldwide, it is significant to understand the relationship of the U.S. biotech industry and its ability to obtain funding to the biotech industries in other countries. While the industry is more mature and better funded in the U.S., there

is important scientific work being undertaken worldwide and researchers must collaborate on a worldwide basis. The U.S. biotech industry has grown and matured in recent years. In the first half of 2000, U.S. biotech com-

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panies raised \$22.1 billion from private and public financings, well above the \$12 billion raised in all of 1999 and nearly triple the \$8.1 billion raised in 1998.² Furthermore, 58 companies went public in 2000 up from 12 the previous year.³ With more profitable companies and more products on the market, there are many more opportunities for larger deals between biotechs and pharmaceuticals, biotechs and biotechs and biotechs and e-health groups.

A recent international transaction announced in January 2001, involving large biotech and big pharma, was Bayer AG's



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\$1.5 billion package with drug discovery and development company CuraGen Corporation.⁴ The new partners have committed to the clinical development of 12 drug candidates. They will split up \$1.34 billion in development costs over 15 years.⁵ Another large international transaction was the recent agreement among F.Hoffmann-La Roche Ltd, Genentech Inc. and OSI Pharmaceuticals, Inc., giving Genentech and Roche the rights to a promising new cancer drug developed by OSI.⁶ Genentech and OSI are to employ an essentially equal cost and profit sharing arrangement for commercialization in the U.S., while Roche is expected to pay royalties on net sales to OSI in markets outside the U.S.⁷ Under the agreement, Genentech and Roche agreed to purchase \$35 million of OSI common stock and pay up-front fees. Although OSI has retained certain co-promotion rights, Genentech will be primarily responsible for commercializing the drug in the U.S.⁸ In another transaction, Merck & Co. will pay Isis Pharmaceuticals Inc. up to \$50 million in licensing and milestone fees for Isis' preclinical Type II diabetes antisense drug candidates.⁹

Genomics companies are entering into transactions that will enable them to have downstream drug development capabilities. Celera Genomics Group acquired Axys Pharmaceuticals and Lexicon Genetics recently acquired Coelacanth Corporation. Celera seems to have acquired Axys in large part for its oncology focus¹⁰ and Lexicon Genetics acquired Coelacanth for its libraries targeted at GPCRs and ion channels, focus areas for Lexicon's target generation efforts.¹¹

EUROPEAN GROWTH

The European sector has undergone similar growth. The year 2000 was heralded as the best ever for the European biotech industry. Fundraisers, valuations, revenues, employment and the number of companies all reached record levels, according to Ernst & Young's eighth annual European Life Sciences Report.¹² While the European sector is earlier in its life cycle than its counterpart in the U.S., many view it as poised to reach critical mass.¹³ Up from 1999, four times as much money has been raised, and more than twelve companies have a war chest of more than \$100 million versus only one company last year. There has also been an increase in corporate alliances and mergers and acquisitions, which were up 54% from 1999. Some argue that this increase indicates a global trend towards greater interaction among the larger biotech markets and especially between the U.S. and Europe.¹⁴

Greater interaction between Europe and the U.S., some argue, is inevitable.¹⁵ According to Ernst and & Young's integration report, there is a "yawning chasm" in resources

between Europe and the U.S. for biotech companies and a threat being mounted on the UK's sector dominance on the European side of the Atlantic.¹⁶ Nevertheless, the U.S. industry is bigger and better funded than Europe.¹⁷ Potential for intellectual property in the UK and Scotland is great, but there is not the critical mass necessary to exploit it.¹⁸ Thus, the driving effect for consolidation and collaboration continues.

Technology is moving at a fast pace and the data is growing exponentially. Companies must therefore act quickly and decipher many issues that may prevent them from attaining critical mass to ensure continued growth and development.

All of this international consolidation brings about many legal and business issues that must be considered. The European and U.S. regulatory systems differ greatly in many aspects. Two of the over-arching issues facing transatlantic collaborations and mergers which are approached differently by the U.S. and Europe are the antitrust laws and various patent and intellectual property issues, most of which are discussed below.

PATENT MISUSE

The doctrine of patent misuse has evolved over the past eighty years by way of a consistent line of case law holding that a patent owner who uses a patent to engage in conduct out-

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side the scope of the patent grant misuses the patent.¹⁹ Such misuse occurs when a patent holder improperly seeks to expand the physical or temporal scope of the patent. Courts employ general equitable standards when applying the doctrine, and if

patent misuse is found, the patent owner will be barred from enforcing the patent. In addition, a person sued for patent infringement will not be liable, even if the patent is valid and infringed.²⁰

Certain practices which have been found to constitute patent misuse include refusals to use or license a patent, imposition of royalties after a patent expires, calculation of royalties on a basis broader than the rights granted, mandatory package licenses (licensee obligated to take a license under other patents) and tying arrangements (patent owner demands that a licensee buy or lease unpatented components or demands that a licensee not use the goods or services of others).²¹ With the passage of the Patent Misuse Reform Act of 1988, Congress limited the misuse affirmative defense with respect to certain activities by a patent owner, including the refusal to license a patent and conditioning patent rights where the patent owner is without market power.²²

MANDATORY PACKAGE LICENSES

A patent owner may desire to license a group of patents in one package license, particularly if all of the patents relate to a certain product or are applicable to a certain field. However, such a license may not be permitted if in order to obtain the desired patents, a licensee must take a license to patents it does not want.²³ Mandatory package licensing could be deemed misuse because it enables an extension of the scope of the patents being tied together.²⁴ However, the Patent Misuse Reform Act allows a patent owner to condition a license to a patent on the acquisition of a license to another patent "unless, in view of the circumstances, the patent owner has market power in the relevant market for the patent . . . on which the license . . . is conditioned."²⁵ Thus, a patent owner must consider whether a licensee would be coerced or compelled to take a license to patents it does not desire.²⁶

When negotiating a license agreement for a package license, a patent owner should carefully consider how it approaches and interacts with a potential licensee during the drafting and negotiating period in order to be able to defend a subsequent claim of coercion. Good faith negotiations should take place and a patent owner should refrain from immediate steadfast refusal in licensing fewer patents in a package.²⁷ A patent owner should also explain why the package is mutually convenient and gain the acceptance of the licensee.²⁸ The package license should contain complementary patents, and the patent owner should consider granting the licensee a unilateral right to terminate the licenses to one or more patents.²⁹ In addition, alternative scenarios and various licensing programs should be considered and discussed before a package license is finalized.³⁰ Finally, economic coercion by the patent owner should be avoided.³¹

EXTENSION OF ROYALTIES BEYOND THE LIFE OF A PATENT

In 1964, the United States Supreme Court in *Brulotte v. Thys Co.* ruled that a contract in which the royalty remained the same after the expiration of the patent as during the life of the patent was unenforceable as a matter of law as to royalties after such expiration.³² In that case, the Court concluded that the licensor was using licenses to project the licensor's monopoly beyond the patent period.³³ However, the Court distinguished contracts that require royalties that accrue during the pre-expiration period to be paid during the post-expiration period.³⁴

Although the Supreme Court in *Brulotte* determined that a licensor cannot force royalties to be paid beyond the life of a patent, courts have also determined that royalties may be

payable until the expiration of the last to expire of a group of patents.³⁵ However, as noted in the discussion on Mandatory Package Licenses, a determination of coercion is relevant to the lack of diminution of royalties as patents included in a package license expire. Courts have found that absent coercion, the royalty rate of a package license need not diminish as patents included in such license expire.³⁶

When negotiating royalty provisions for a license agreement, similar approaches to those mentioned under Mandatory Package Licensing are appropriate. For instance, the royalty plan should be documented to show the mutual benefits to the parties.³⁷ Other considerations include deferring royalties beyond the patent's life,³⁸ permitting licensees to terminate at will,³⁹ requiring a minimum acceptable annual royalty during the life of all patents in a license package⁴⁰ and basing the royalty on those portions of product or process that infringe an unexpired license to the patent.⁴¹

CHALLENGING THE VALIDITY OF A PATENT

In 1969, the Supreme Court in *Lear, Inc. v. Adkins*, ruled that a licensee was not stopped from asserting patent invalidity if the licensee was sued by the licensor for failing to pay royalties.⁴² Prior to *Lear*, licensee estoppel was permitted under the theory that a licensee should not be permitted to enjoy the benefits of an agreement while at the same time urging that the

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patent underlying the agreement is void.⁴³ The Court in *Lear* found that "the technical requirements of contract doctrine must give way before the demands of the public interest in the typical situation involving the negotiation of a license after a patent has issued." However, the enforceability of provisions allowing the licensor to terminate a license if the validity of the patent forming the basis of the agreement is challenged remains uncertain. Various decisions by the United States Court of Appeals for the Federal Circuit over the past fifteen years have departed from the *Lear* holding, and while not directly ruling on the validity of such provisions, have implicitly indicated that they may be enforceable.⁶⁴

Although licensees may challenge the validity of a patent, they are subject to some restrictions. For instance, the *Lear* decision allows licensees to stop paying royalties on a patent they believe is invalid and then defend an action for payment by asserting patent invalidity.⁴⁵ However, courts interpreting *Lear* have focused on whether the failure to pay royalties is connected to the challenge to the validity of the patent.⁴⁶ Courts have held that a licensee must notify the licensor that it is suspending royalty payments because it questions a patent's validity if the licensee wants to preserve patent

invalidity as a litigation defense to a claim for failure to pay royalties.⁴⁷ In addition, litigation and settlement stipulations may require a licensee to make royalty payments even if the patent is determined to be invalid at a later date.⁴⁸ Courts have also held that due to the principals of *res judicata* (claim preclusion), a licensee who acknowledges the validity and infringement of a licensor's patent as part of a consent decree terminating an infringement suit may not subsequently challenge the patent.⁴⁹

STATE AND FEDERAL LAW CONSIDERATIONS

The United States federal district courts have exclusive jurisdiction in actions relating to patents.⁵⁰ In addition, the United States Court of Appeals for the Federal Circuit has exclusive jurisdiction of appeals from final decisions of the federal district courts.⁵¹ Generally, matters of contract law and interpretation are controlled by state law.⁵² However, substantive and procedural issues that pertain to or are "unique to patent law" and "intimately involved in the substance of enforcement of the patent right" are governed by the Federal Circuit.⁵³

Approximately ten years ago, Congress enacted a statute that allows the enforcement provisions of the Federal Arbitration Act⁵⁴ to apply to patent contracts (e.g. settlement and license agreements).⁵⁵ Thus, patent arbitration awards must be in accordance with the Federal Arbitration Act. However, it should be noted that a challenge to the award of arbitration fees is not "unique to patent law" or "intimately involved" in its substance, and is therefore a matter of state contract law.⁵⁶

JOINT PATENT OWNERSHIP

Each co-owner of a United States patent is generally free to make, use, offer to sell, sell or import patented inventions without taking into account the desires of other co-owners.⁵⁷ In addition each co-owner has a right to license the patent to third parties, and such right to license does not require the consent of the other joint owners.⁵⁸ Although a co-owner has the right to use and license a patent, only non-exclusive licenses may be granted by a co-owner unless the joint owners of the patent agree otherwise.⁵⁹ Furthermore, without such an agreement, one co-owner can deprive another co-owner of the right to sue and collect damages for infringement by granting a license to the infringer.⁶⁰ However, such an infringer may still be liable for infringement that occurred before the license was granted.⁶¹ Thus, the joint owners of a patent must enter into the appropriate agreements in order to generally enforce a patent.⁶² In addition, the necessary

agreements should be made between the patent owners and any licensee of a patent in order to ensure that the licensee receives all of the rights granted under the license.⁶³

ANTITRUST CONCERNS

Joint venture and collaboration agreements that promote innovation and technological advancement in an efficient and economically advantageous manner are generally acceptable under U.S. law. Agreements that by their nature could adversely impact the market, such as exclusive licenses, pooling arrangements or grant backs, may be scrutinized by the United States Department of Justice (the "DOJ") and the United States Federal Trade Commission (the "FTC," collectively with the DOJ, the "Agencies"), the two agencies responsible for enforcing the antitrust laws.

Joint venture and collaboration agreements involve activities such as research and development, manufacturing, production, marketing, licensing, distribution, sales or purchasing. In the case of the licensing of intellectual property, which is frequently a component of a joint venture or collaboration agreement, an obvious tension lies between the laws protecting intellectual property rights and the laws

concerning antitrust. On the one hand, laws protecting intellectual property rights, which are most evident in the area of patent law, may serve to create a monopoly.⁶⁴ While on the other hand, antitrust laws proscribe the existence of such mono-

polies.⁶⁵ The Agencies have come to recognize that in certain cases such agreements have competitive benefits, but also recognize that anticompetitive effects may directly or indirectly result from such agreements.

The antitrust laws as promulgated under the Sherman Act⁶⁶ prohibit any contract, combination in form of trust or otherwise, or conspiracy in restraint of trade or commerce; and prohibit every person who monopolizes or attempts to monopolize any part of trade or commerce among the several States. To provide some clarity to the rather broad antitrust laws and its enforcement, the Agencies have published various guidelines. Guidelines specifically in the area of joint ventures and collaborations consist of the *Antitrust Guidelines for the Licensing of Intellectual Property* in April 1995 (the "IP Guidelines") and the *Antitrust Guidelines for Collaborations Among Competitors* in April 2000. For transactions that include the acquisition, disposition or transfer of assets or voting securities, the Hart-Scott-Rodino Antitrust Improvements Act of 1976⁶⁷ (the "HSR Act") may also apply.⁶⁸

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PER SE ILLEGAL

Agreements that restrict competition and that are not related to an efficiency-enhancing integration of economic activity are generally considered to be *per se* illegal by the Agencies and may subject the participants to civil, as well as criminal penalties. These typically include agreements to fix prices or output, rig bids, or share or divide markets by allocating customers, suppliers, territories or lines of commerce and maintain minimum resale price.

Regardless of whether the agreement in question is subject to the *per se* illegality standard or the rule of reason standard, described below, the antitrust analysis is heavily dependent on the definition of the relevant market place the agreement affects. In the context of intellectual property licenses and agreements, the Agencies generally recognize three markets; goods markets, technology markets, and innovation markets.⁶⁹

RULE OF REASON

Agreements not challenged as *per se* illegal are analyzed under the Rule of Reason. Thus, if an agreement has the effect of restraining trade but is reasonably related to an efficiency-enhancing integration and reasonably necessary to achieve its procompetitive benefits, the Agencies will analyze the agreement under this "Rule of Reason" standard.⁷⁰ The primary focus in determining which analysis applies is whether the agreement contributes to an efficiency-enhancing integration of economic activity.⁷¹

Under Rule of Reason analysis, the Agencies consider whether a restraint has anticompetitive effects and, if so, whether the restraint is reasonably necessary to achieve procompetitive benefits and whether those benefits outweigh its anticompetitive effects.⁷²

Joint venture relationships generally come in two forms: horizontal relationships, where the parties are competitors; and vertical relationships where the parties operate in different phases of the overall production and distribution process.

While agreements that create either relationship may be analyzed under the Rule of Reason standard, the Agencies adopt a more lenient approach to vertical agreements, under which most of the joint venture and collaboration agreements in the biotechnology area fall into. Agreements with respect to intellectual property between direct competitors may sometimes be treated as vertical agreements if the Agency finds that one party's technology is so superior to its competitor's technology that the competitor's technology is not a "close substitute" and the competitor is not likely to develop a competing technology in the absence of the license.⁷³

The Agencies recognize that vertical agreements may still impair competition due to the risk of coordinated interaction in the market place. The Agencies pay particular attention as to whether the agreement conveys *exclusive* rights since any such *exclusivity* may harm competition by foreclosing access to a necessary input or raise the cost of that input.⁷⁴ The Agencies have created a "safety zone" specifically for nonexclusive licensing agreements for intellectual property if (1) the restraint is not one that ordinarily is subject to *per se* treatment (i.e. market allocation or price fixing) and (2) the parties to the license collectively possess a market share of 20% or less in each of the relevant markets affected by the restraint.⁷⁵ If such factors are met, the Agencies will rarely challenge the anticompetitive effects of the agreement. It is important to realize that regardless of the particular tests that apply to a joint venture agreement, the Agencies' analysis is "based on the factual circumstance prevailing at the time of the conduct at issue," which can make it difficult to predict how safe the joint venture arrangement is from violating the antitrust laws.

On the other hand, joint ventures and collaborations among competitors that satisfy the following conditions may be considered a horizontal merger and analyzed under the Horizontal Merger Guidelines, as amended in 1997: (1) the parties are competitors in the relevant market place; (2) the

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arrangement involves an efficiency-enhancing integration of economic activity in the relevant market; (3) the integration eliminates all competition among the participants in the relevant market; and (4) the arrangement does not terminate within a sufficiently limited period (usually 10 years) by its own specific and express terms.⁷⁶ The analysis of a horizontal merger involves an assessment of market concentration, potential adverse competitive effects, entry, efficiency and failure in the market. Such an assessment is aimed at answering the question of whether the merger is likely to create or enhance market power or facilitate its exercise.⁷⁷ As a caveat, however, the IP Guidelines are only an indication of government enforcement policy based on the case law and are not binding on the courts, DOJ, FTC, state governments or private parties.

The Cooperative Research Act,⁷⁸ which was passed by Congress in 1984, specifically provides that joint venture agreements will be analyzed under the Rule of Reason standard. The definition of "joint venture," however, is fairly narrow, and excludes agreements among competitors, or agreements that will result in restricting trade such as restricting the sale, licensing or sharing of inventions, developments, products, processes or services not developed or produced by the joint venture and research and development if not reasonably related to the proportion of intellectual property contributed to the joint venture.

TRANSFER OF ASSETS OR VOTING SECURITIES

The HSR Act requires parties acquiring or disposing of certain voting securities or assets to provide notice of the transactions to the Agencies before the closing of the transaction and await the expiration of a statutory waiting period prior to consummating the transaction.⁷⁹ This notice requirement allows the Agencies the opportunity to evaluate the impact of those transactions that fall under the scope of the HSR Act and challenge the anticompetitive transactions prior to consummation.

The threshold for being subject to the notice requirement under the HSR Act is principally based on the determination of two factors: (1) the size of the transaction test and (2) the size of the parties.⁸⁰ The following transactions will be subject to the notice requirement under the HSR Act:

1. Transactions valued at more than \$200 million.
2. Transactions valued at less than \$200 million but more than \$50 million and where one party has \$100 million or more in assets or revenue and another party has \$10 million or more in assets or revenues.

The initial waiting period is 30 days, after which, if the parties have not been contacted by the Agencies, it is presumed that the transaction is free from further inquiry from

the Agencies and can be consummated.

Threshold Antitrust concerns under HSR are as follows:

1. Greater than \$50 million in assets or voting securities held after the transaction;
2. Greater than or equal to \$100 million in assets or voting securities held after the transaction;
3. Greater than or equal to \$500 million in assets or voting securities held after the transaction;
4. Greater than or equal to 25% of the voting securities of the issuer and greater than or equal to \$1 billion of the voting securities of the issuer;
5. Greater than or equal to 50% of the voting securities of the issuer and greater than \$50 million of the voting securities of the issuer.

In biotech agreements, it is not always clear as to whether the thresholds are evident because this may require an analysis of contingency payments in terms of whether or not they will occur and the approximate amount of such payments. Examples of biotech agreements where these issues arise include a pharmaceutical company investing in a biotech or an exclusive license with a right to sell.

ENDNOTES

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2. *Biotech Industry Flexes New Muscles*, The New York Times, August 24, 2000, at C1.
3. Joan Harrison, *Sizing up Biotech M&A as Industry Dynamics Continue to Change*, Mergers and Acquisitions J. (2001).
4. *Bayer and CuraGen Enter into Two Landmark Agreements*, Nasdaq News, January 16, 2001.
5. *Bayer and CuraGen Close Landmark Drug Discovery, Development, and Pharmacogenomic Agreements*, PR Newswire, February 22, 2001. The authors' firm was counsel to CuraGen.
6. *OSI Pharmaceuticals, Genentech and Roche to Develop and Commercialize OSI-774, OSI's Lead Cancer Drug*, PR Newswire, January 8, 2001. The authors' firm was counsel to OSI.
7. *Randell Osborne, OSI's Double Deal for Cancer Drug: Genentech, Roche Pay up to \$187M*, BioWorld Today, January 9, 2001, at p.1.
8. Osborne, *supra* note 7, at 4.
9. *Merck Licenses Isis Compound for Diabetes in \$50 M Alliance*, Bio World Today, May 24, 2001, at p. 1.
10. *Lexicon Genetics to Acquire Coelacanth Corporation*, PR Newswire, June 13, 2001.
11. Scott Hensley, *Celera to Buy Axis for \$174 Million; Move Bolsters Drug-Production Plans*, Wall St. J., June 14, 2001.
12. *European Biotech Sector has Record Year in 2000 - Ernst & Young*, AFX Europe, April 26, 2001.
13. *Robertson Stevens Provides Outlook on European Life Sciences Sector*, Financial News, November 27, 2000.
14. Glenn Crocker, *Capital is Key to Making the Biotech Sector Fulfill Its Potential*, The Scotsman, April 26, 2001, at 5.
15. Croker, *supra* note 14, at 5.
16. Croker, *supra* note 14, at 5.
17. Croker, *supra* note 14, at 5.
18. Croker, *supra* note 14, at 5.
19. See *Motion Picture Patents Co. v. Universal Film Mfg. Co.*, 243 U.S. 502 (1917) (denying relief for infringement because the tying of the use of a motion picture projector containing a patented film feeding mechanism to films made only by patent owner was outside the scope of the patent laws). See Aaron Xavier Fellmeth, "Copyright Misuse and the Limits of the Intellectual Property Monopoly," 6 J. Intell. Prop. L. 1, (1998); See Patent-Antitrust Law § 29 (Raymond C. Nordhaus ed., 3d ed. 1989).
20. See Arnold B. Silverman, "Patent Misuse: Limitations on a Patentee's Rights," 44 No. 8 JOM 54 (1992); Patent-Antitrust Law, *supra* note 19.
21. Barry Evans, "Boundaries Have Changed for Patent Misuse Defense," N.Y.L.J., February 17, 1998, at S6, col. 3.
22. Pub. L. 100-703, § 201 (1988). The Patent Misuse Reform Act modified § 271(d) of Title 35 of the United States Code by adding two clauses which state that a patent owner otherwise entitled to relief for infringement shall not be deemed guilty of misuse by having "refused to license or use any rights to the patent" (35 U.S.C. § 217(d)(4)) or "conditioned the license to rights to the patent or the sale of the patented product on the acquisition of a license to rights in another patent or purchase of a separate product, unless in view of the circumstances, the patent owner has market power in the relevant market for the patent or patented product on which the license or sale is conditioned." (35 U.S.C. § 271(d)(5)). See Evans, *supra* note 21.
23. Sheila J. McCartney, "Licensing Alternatives to Limit Antitrust and Misuse Exposures: Part II," 7 No. 5 J. Proprietary Rts. 16 (1995); See *American Securit Co. v. Shatterproof Glass Corp.*, 268 F.2d 769, 776-77 (3d Cir.) (affirming lower court finding of patent misuse when licensor compels licensee to accept package of patents or none at all), *cert. denied*, 361 U.S. 902 (1959); *Hull v. Brunswick Corp.*, 704 F.2d 1195, 1201 (10th Cir. 1983).
24. For instance, "the term of a valuable, about-to expire tying patent may be extended by licensing it in a package with some insignificant, newly issued tied patent with

- no provision for reducing royalties as the patents in the package expire." *McCartney*, *supra* note 23, at 16.
- 25 35 U.S.C. § 217(d)(5); *see also* Nellie A. Fisher, "The Licensee's Choice: Mechanics of Successfully Challenging a Patent Under License," 6 *Tex. Intell. Prop. L.J.* 1 (1997).
- 26 *See, e.g.*, *Western Elec. Co. v. Stewart-Warner Corp.*, 631 F.2d 333, 338 (4th Cir. 1980) (finding a package license is not unlawful per se or a misuse of the patent, absent coercion), *cert. denied*, 450 U.S. 971 (1981); and *Turbo Mach. Co. v. Proctor & Schwartz, Inc.*, 241 F. Supp. 723, 729-30 (E.D.Pa. 1965) (finding that no misuse exists if a party is not compelled to take license to and pay royalties under unused or subsequently-granted patents), *aff'd*, 362 F.2d 5 (3d Cir. 1966); *but see* *Data General Corporation, et. Al. v. Grumman Systems Support Corporation*, 36 F.3d 1147 (1st Cir. 1994) (finding defendant failed to show that plaintiff engaged in exclusionary conduct by unilaterally refusing to sell licenses or service tools to owners); *Lasercomb America, Inc. v. Job Reynolds*, (4th Cir. 1990) (finding the appellee misused its copyright by attempting to use its copyright to control competition in an area outside the copyright).
- 27 *McCartney*, *supra* note 23, at 17. *See American Securit Co.* 268 F.2d at 769 (finding that the refusal to offer any terms other than the mandatory package is prohibited).
- 28 *McCartney*, *supra* note 23, at 17; *See McCullough Tool Co. v. Well Surveys, Inc.*, 343 F.2d 381, 407 (10th Cir. 1965).
- 29 *McCartney*, *supra* note 23, at 17.
- 30 *McCartney*, *supra* note 23, at 17.
- 31 For example, if the rate for a package license is so much lower than the rate for a single patent, the licensee essentially does not have economic choice. *McCartney*, *supra* note 23, at 17.
- 32 *Brulotte v. Thys Co.*, 379 U.S. 29, 32 (1964). *See Virginia Panel Corp. v. Mac Panel Co.*, 133 F.3d 860, 869 (Fed. Cir. 1997) (noting that courts have identified specific practices, including arrangements in which a patentee effectively extends the term of its patent by requiring post-expiration royalties, as constituting *per se* patent misuse), *cert. denied*, 525 U.S. 815 (1998). *See also* *Boggild v. Kenner, Div. of CPG Products Corp.*, 853 F.2d 465, 469 (6th Cir. 1988); *Meehan v. PPG Ind., Inc.*, 802 F.2d 881, 886 (7th Cir. 1986), *cert. denied*, 479 U.S. 1091 (1987); and *Pitney Bowes, Inc. v. Mestre*, 701 F.2d 1365, 1373 (11th Cir. 1983), *cert. denied*, 464 U.S. 893 (1983), all following *Brulotte*.
- 33 *Brulotte*, 379 U.S. at 33.
- 34 *Id.* at 31. *See also Meehan* 802 F.2d at 883; *Boggild v. Kenner Products*, 776 F.2d 1315. It should be noted that many licenses allocate royalties between patents and know-how and royalties on know-how are collectible after the expiration of the patent. However, if there is not a clear allocation between the two, the licensor may not be able to collect royalties after the patent expires. In order to prevent such a result, the parties could enter into two separate agreements (one for know-how and one for patents). Alternatively, the parties could use one agreement if separate royalty rates for know-how and patents are clearly stated. *McCartney*, *supra* note 23, at 17.
- 35 *See Hull*, 704 F.2d at 1195 (10th Cir. 1983) (stating that there is no legal compulsion to negotiate individual rates and a party is entitled to attempt to negotiate a one-price arrangement with any other willing licensee if convenient to both and not oppressive).
- 36 *See id.*; *Well Surveys, Inc. v. Perfo-Log, Inc.*, 396 F.2d 15, 18 (10th Cir. 1968) (stating that the lack of diminution in royalty rate for the use of one patent without the other patent does not establish coercion), *cert. denied*, 393 U.S. 951 (1968); *American Securit*, 268 F.2d at 769 (mandatory, coercive package licensing is misuse); *Sunrise Medical HHG, Inc. v. AirSep Corp.*, 95 F.Supp.2d 348, 458 (W.D.Pa. 2000) (finding that a licensor did not coercively condition the license upon an agreement that the royalty would not change regardless of the expiration of some of the licensed patents); and *A.C. Aukerman Co. v. R.L. Chaides Constr. Co.*, 29 U.S.P.Q.2d 1054, 1058 (N.D.Cal. 1993) (finding that determination that the agreement was the product of unfair patent leverage is a question of fact).
- 37 *McCartney*, *supra* note 23, at 19. *See Hull*, 704 F.2d at 1201 (noting that the parties' royalty structure was an efficient and mutually beneficial arrangement for a number of years).
- 38 *Brulotte*, 379 U.S. at 31.
- 39 *But see Hull*, 704 F.2d at 1201 (noting that the existence of termination clause does not in itself eliminate the illegal nature of an oppressive license agreement and citing *American Securit Co. v. Shatterproof Glass Corp.*, 154 F.Supp. 890 (D.Del. 1957), *aff'd*, 268 F.2d at 769.
- 40 *McCartney*, *supra* note 23, at 19.
- 41 *McCartney*, *supra* note 23, at 19. *See Lightware Technologies, Inc. v. Corning Glass Works*, 19 U.S.P.Q.2d 1838, 1840 (S.D.N.Y. 1991) (defendant avoided a finding of conditioning by "demonstrating that its licensing agreements were the product of mutual negotiations"); *Well Surveys*, 396 F.2d at 17.
- 42 *Lear, Inc. v. Adkins*, 395 U.S. 653, 656 (1969).
- 43 *Id.* *see e.g.* *Automatic Radio Mfg. Co. v. Hazeltine Research, Inc.*, 339 U.S. 827 (1950); Under European Union competition rules, license provisions giving a licensor the right to terminate a license agreement if the licensee challenges the validity of the licensed patent within the European Union is for all intents and purposes permitted, in that the licensor can terminate when invalidity is asserted by the licensee. Raymond S. Fersko and Jesse A. Lynn, "The art of cross-pond negotiations: Finding a foreign partner," 5 No. 3. *J. Com. Biotech.* 191, 195 (1999).
- 44 Fersko and Lynn, *supra* note 43, at 197 (citing Christian Chadd Taylor, "No-Challenge Termination Clauses: Incorporating Innovation Policy and Risk Allocation into Patent Licensing Law," 69 *Ind. LJ* 215, 246 (Winter 1993). *See Flex-Foot, Inc. v. CRP, Inc.*, 238 F.3d 1362 (Fed. Cir. 2001) (holding that a settlement agreement in which an alleged infringer agreed not to challenge a patent's validity in the future was not void as against public policy).
- 45 *Lear*, 395 U.S. at 673-674.
- 46 *Hull*, 704 F.2d at 1203.
- 47 *Id.* (citing cases from the United States Court of Appeals for the Third, Sixth, Seventh and Ninth Circuits).
- 48 *Flex-Foot, Inc.*, 238 F.3d at 1369 (citing *Hemstreet v. Spiegel, Inc.* 851 F.2d 348, 349-50 (Fed. Cir. 1988) (holding that a dismissal based upon a settlement order in which the issues of validity, enforceability and infringement of the patents in the suit were finally concluded and disposed of barred a subsequent challenge to the validity and enforcement of those patents by the same party)).
- 49 *Foster v. Hallico Mfg. Co.*, 947 F.2d 469, 477 (Fed. Cir. 1991).
- 50 28 U.S.C. § 1338.
- 51 28 U.S.C. § 1295. As stated by the Supreme Court in *Sears, Roebuck & Co. v. Stiffel Co.*, 376 U.S. 225, 230-31 (1964) "the patent system is one in which uniform federal standards are carefully used to promote invention while at the same time preserving free competition" and "the purpose of Congress to have national uniformity in patent and copyright laws can be inferred from such statutes as that which vests exclusive jurisdiction to hear patent and copyright cases in federal courts." *Id.*
- 52 *American Medical Systems, Inc. v. Medical Engineering Corp.*, 6 F.3d 1523, 1532 (Fed. Cir. 1993), *cert. denied*, 511 U.S. 1070 (1994) (citing *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1241 (Fed. Cir. 1989), *cert. denied*, 493 U.S. 853 (1989) and *Universal Gym Equip., Inc. v. ERWA Exercise Equip. Ltd.*, 827 F.2d 1542, 1550 (Fed. Cir. 1987).
- 53 *Amana Refrig., Inc. v. Quadlux, Inc.*, 172 F.3d 852, 855-56 (Fed. Cir. 1999) (citations omitted); *See Flex-Foot, Inc.*, 238 F.3d at 1365.
- 54 9 U.S.C. § 1 et seq.
- 55 35 U.S.C. § 294. Title 35, Section 294(a) of the United States Code states that "A contract involving a patent or any right under a patent may contain a provision requiring arbitration of any dispute relating to patent validity or infringement arising under the contract. In the absence of such a provision, the parties to an existing patent validity or infringement dispute may agree in writing to settle such dispute by arbitration. Any such provision or agreement shall be valid, irrevocable, and enforceable, except for any grounds that exist at law or in equity for revocation of a contract." *Id.*
- 56 *Flex-Foot, Inc.*, 238 F.3d at 1365.
- 57 35 U.S.C. § 262. Title 35, Section 262 of the United States Code provides that "In the absence of any agreement to the contrary, each of the joint owners of a patent may make, use, offer to sell, or sell the patented invention within the United States, or import the patented invention into the United States, without the consent of and without accounting to the other owners." *Id.*
- 58 *Schering Corp. v. Roussel-UCLAF SA*, 104 F.3d 341, 344 (Fed. Cir. 1997) (citing *Willingham v. Star Cutter Co.*, 555 F.2d 1340, 1344 (6th Cir. 1977) ("a co-owner of a patent can even grant a license to a third party without consent of the other owners") and *Talbot V. Quaker State Oil Ref. Co.*, 28 F.Supp. 544, 548 (W.D.Pa. 1938) (a co-owner "may make use of and sell specimens of the patented invention and may license others to do so; and neither he nor his licensees can be enjoined from a continuance in doing so"), *aff'd*, 104 F.2d 967 (3d Cir. 1939)). The joint patent laws are only applicable in the United States. The rules applicable to jointly owned patents are different in various foreign jurisdictions. For instance, in Canada, a court has held that a patent co-owner has no right to license a patent to a third party without

- consent of the other co-owners (although such co-owner could exploit the patent for itself). Raymond S. Fersko, "Bionegotiation: Points to Consider in Negotiating Global Research & Development Agreements," 4 No. 4 J. Biolaw & Bus (2001) (citing *Forget v. Specialty Foods of Canada, Inc.*, 62 C.P.R.3d 537 (B.C.Ct.App. 1995)).
- 59 See Fersko and Lynn, *supra* note 43.
- 60 *Schering Corp.*, 104 F.3d at 345.
- 61 *Schering Corp.*, 104 F.3d at 345. In *Ethicon, Inc. v. U.S. Surgical Corp.*, 135 F.3d 1456 (Fed. Cir. 1998), the court found that one co-owner could not release an alleged infringer from liability for past accrued damages to another co-owner (by granting a retroactive license) but could only release the alleged infringer from liability to itself and grant a prospective license. *Id.* at 1467.
- 62 For instance, the patent co-owners could agree that no one will make, use, sell, import or license the patent without the consent of the other parties. Fersko and Lynn, *supra* note 43.
- 63 Fersko and Lynn, *supra* note 43.
- 64 Intellectual property for the purpose of antitrust analysis includes patent, copyright and trade secret law, and of know-how, but does not include trademark licensing. U.S. Department of Justice and the Federal Trade Commission Antitrust Guidelines for the Licensing of Intellectual Property (April 6, 1995) § 1.02 [hereinafter IP Guidelines].
- 65 Daniel G. Swanson, "U.S. Intellectual Property Law and Antitrust Law: An Introduction and Overview," International Bar Association 2000 Conference, 17-22 September 2000, at 1, citing *U.S. v. Westinghouse Elec. Corp.*, 648 F.2d 642 (9th Cir. 1981).
- 66 15 U.S.C. § 1 *et seq.*
- 67 15 U.S.C. § 18a.
- 68 See also DOJ and FTC Antitrust Enforcement Guidelines for International Operations (1995); National Cooperative Research Act of 1984 and the National Cooperative Research and Production Act of 1993 (15 U.S.C. §§ 4301-06).
- 69 IP Guidelines, *supra* note 64, § 3.2.
- 70 Federal Trade Commission and the U.S. Department of Justice Antitrust Guidelines for Collaborations Among Competitors (April 2000) § 3.2 [hereinafter Collaborations Guidelines].
- 71 IP Guidelines, *supra* note 64, § 3.4.
- 72 IP Guidelines, *supra* note 64, § 3.4.
- 73 Swanson, *supra* note 65, at 10.
- 74 IP Guidelines, *supra* note 64, § 4.1.
- 75 IP Guidelines, *supra* note 64, § 4.3.
- 76 Collaborations Guidelines, *supra* note 70 § 1.3.
- 77 U.S. Department of Justice and Federal Trade Commission Horizontal Merger Guidelines (April 8, 1997), § 0.2.
- 78 15 U.S.C. §§ 4301-06.
- 79 For the purposes of HSR analysis, patent rights are treated the same as any other tangible asset.
- 80 "Party" means the ultimate parent and all of its controlled entities.