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Laws and Policies Affecting Global Collaboration and License Agreements

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The number of global collaborations is increasing as organizations look to obtain access to innovation from a wide variety of parties to fill their development pipeline. Intellectual property creation and the allocation of intellectual property rights are central to these collaborations. Therefore, it is imperative that the parties have a clear understanding of the applicable laws affecting these intellectual property rights and the agreements.

Most intellectual property collaboration and license agreements are written on the basis of models from Europe or the US that attempt to provide legal certainty through the express terms of the agreement. Having an understanding of the legal landscape affecting these agreements decreases the likelihood that the parties will have to restructure the business deal during final legal and regulatory review in order to effectuate their intent.

This article looks at some of the fundamental differences between the US and European legal systems affecting collaboration and license agreements, including intellectual property ownership, compensation, bankruptcy, and competition/anti-trust.

Contract Law in the United States

In the United States, the laws of individual states govern agreements, which can lead to variation on the enforcement of the terms, especially if the agreement is silent on the intent of the parties. There are also issues of federal law that govern certain aspects in the agreement, such as its assignability.[1] In general, a reasonably detailed license agreement will address with explicit terms the major legal points that will vary among the states' laws or be affected by federal law, thereby insulating the parties against the risk that their terms will not be effectuated.

Contract Law in Europe

As explained above, most collaboration and license agreements are written on the basis of English or US common law contract models irrespective of the governing law. In Europe, the United Kingdom sits on its own as a common law system while the rest of Europe has developed civil law systems. The civil law systems look to render justice in specific cases, and there is interference by the governing law, rather than reliance on the predictability and certainty of the common law systems. Therefore, it is important to understand the differences that exist between civil and common law jurisdictions so that the parties' expectations can be aligned. The common law model contracts may be ineffective or redundant in parts if the law governing the agreement is based on a civil law system. In addition, the parties should not overlook the substantial nuances that exist between civil law countries.

Statutory Provisions Affecting IP Ownership and Compensation

The lack of global harmonization of intellectual property laws, particularly as they relate to patent law, requires that care be taken in expressly stating each party's ownership rights in collaboration intellectual property.

Article I, Section 8 of the US Constitution provides that US patent rights belong to the inventor, the one who conceived at least one of the claimed inventions. In the United States, coinventors of patent rights are co-owners, absent an agreement to the contrary. Inventors may assign their rights in their inventions, and it would be common in the United States to have such assignment agreement as a term in their employment agreement. Several states also have employee patent acts that limit the enforceability of an employment agreement that requires assignment of inventions beyond the scope of the subject matter specified in the act.[2]

Differing regimes in Europe means that the original owner of an invention arising from collaborative research could be an institute, individual researcher, student, industrial partner, or a combination of these. In most jurisdictions, the employer is the owner of employees' inventions created while carrying out their work. In the United Kingdom, for example, the employer will own a patent if the invention arises from "normal duties" or "duties specifically assigned."[3] However, this only applies to employees, so students, consultants, and directors will own any inventions they make unless contractual provisions determine otherwise.

In Germany, the ownership of inventions is governed by the Employees Inventions Act.[4] The employee inventor is the owner of any invention he or she makes and must report the invention to the employer. The employer automatically acquires the rights to the invention within a certain time period unless it actively notifies the employee that it does not want the rights. In some European countries (*e.g.*, Italy and Sweden) the employer is not always the owner of inventions that an employee creates while performing normal work duties because professors' privilege applies. Professors' privilege means that academics and researchers are the first owners of their inventions. In these countries, there is no equivalent of the Bayh Dole Act of the United States,[5] but some countries within Europe do have certain automatic and pre-emptive rights associated with public funding, so this must be examined thoroughly in any country where individual collaborators are employed or performing the work.

The issue of joint ownership often is thought of as an equitable arrangement among the parties, but this can be a legal minefield to the unwary as there is no legal concept of joint ownership in Europe and scope is determined by national laws. The precise consequences of co-ownership differ as between different types of intellectual property rights and between different countries. Notwithstanding a choice of law clause, it is likely that the legal effects of joint ownership will be decided according to the intellectual property laws of the country granting the intellectual property right. For example, under the laws of the United States, each co-owner has the equal and undivided right to practice and convey rights without accounting to or obtaining the permission of another owner. [6] Only asserting the patent rights requires joining the owners.

This differs from the patent laws in other countries, where co-applicants have the right to practice the patent rights, such as in Germany and the United Kingdom, but prior permission of all co-owners is required to convey and assert rights. For this reason, co-owners usually have a written agreement, often the collaboration and license agreement, that expressly states how the co-owners are permitted to grant licenses and make other conveyances, how decisions will be made regarding the filing, prosecution, defense, maintenance and enforcement of the rights, and how the costs associated with those activities will be allocated. Unless the parties agree on the rights and procedure and memorialize their agreement in writing, they will be at risk relying on default rules in which there are substantial differences in the way in which countries deal with the ownership of inventions and jointly owned rights.

The parties also may need to address compensation payable to inventors. While this may not be as much an issue in the United States, compensation requirements vary significantly across Europe in terms of eligibility, amount, and the frequency of awards. It is questionable whether parties can override the compensation rules of any given country so they do need to be familiar with the relevant national regimes in question when negotiating the agreement. For example, in countries such as the United Kingdom, the Netherlands, France, Italy, Austria, and Spain compensation is provided for in patent legislation. In the United Kingdom, compensation must be made to employees when a patent is of "outstanding benefit."[7] In 2009, the first judgment was awarded to inventors for compensation on a patent of outstanding benefit.[8] Due to the size of the award (a combined total 1.5 Million GBP of the 50 Million GBP profit), it was anticipated that the floodgates would open for other claims, particularly in patent intensive industries such as the pharmaceutical industry. However, there has been only one other case for which the size of the award has yet to be determined.[9] In France, compensation claims are reported to be more frequent but lower in scale.[10]

In other countries, Germany, Denmark, and Finland, for example, there are specific employee compensation laws. Germany's Employee Inventions Act is accompanied by Ministerial Guidelines on compensation for inventions in the private sector. If an employer claims ownership of an invention then it must pay reasonable compensation to the employee, which is determined in accordance with the Ministerial Guidelines. If the employer and employee cannot agree on the level of compensation within a certain time, then the employer must calculate the level of compensation and provide a written declaration to the employee accompanied by the reasons for the calculation. If the employer and employee cannot agree then the dispute can go to arbitration.

The Bayh-Dole Act[11] in the United States is another important statutory consideration in collaboration and license agreements as the inventions giving rise to the rights also may be funded by the US government. Under the Bayh-Dole Act, grantees of funding are permitted to retain title to inventions conceived or first actually reduced to practice with government funding. In exchange, the US government has non-exclusive license to practice and have practiced those inventions and requires compliance with certain restrictions. For example, if the grantee is a non-profit institution of higher education and grants an exclusive license under the US rights, then the licensee and others obtaining rights therefrom must substantially manufacture the product and the product produced through the use of subject inventions in the United States, unless waived.[12] This can be an important component to consider in a global pharmaceutical license especially because the government's rights may arise after the execution of the license agreement for patent rights that were not subject to these restrictions.

Antitrust and EU Competition Law Issues That May Trump Agreement Provisions

Statutory provisions in the United States play a significant role in whether the parties' intent expressed in the collaboration and license agreement will be enforced. One such area occurs at the intersection between antitrust concerns and licensing terms. Price fixing and preventing market division among horizontal competitors are some examples of terms in the collaboration and license agreement that would be unenforceable because they are per se violations of US antitrust law.[13] Other terms in the collaboration and license agreement, such as tying, tied-in, or bundling unpatented products with the license to patent rights may constitute antitrust violations as well as patent misuse.[14] Patent misuse is an equitable defense to patent infringement, restraining practices that did not in themselves violate any law, but that drew anticompetitive strength from the patent right, and thus were deemed to be contrary to public policy.[15] Another example of patent misuse is requiring the licensee to pay royalties after the expiration of the patent for post-expiration use.[16]

Conversely, there are a number of likely acceptable restraints of trade commonly used in structuring global pharmaceutical licenses that are not per se violations of US antitrust laws, such as grant-back agreements under which the licensor has access to the licensee's improvements.[17] For purposes of structuring the license agreement, consider the rule of reason, which determines legality by: "[W]hether the restraint imposed is such as merely regulates and perhaps thereby promotes competition or whether it is such as may suppress or even destroy competition."[18]

European competition law affects parties that grant licenses under European intellectual property rights, regardless of whether the parties are based in Europe. The basic tenet of European competition law is set out in Article 101 of the Treaty on the Functioning of the European Union, which prohibits agreements and arrangements that restrict competition within the EU internal market, except in certain cases in which the benefits to consumers outweigh the negative effects of the restriction. In other words, the European Union adopts a rule of reason approach similar to the United States. EU legislation provides a safe harbor to certain technology license agreements by way of the Technology Transfer Block Exemption Regulations (TTBER).[19] If the agreement in question does not exceed certain market thresholds (thresholds differ for competitors and non-competitors) and does not contain any problem clauses (hard-core restrictions and excluded restrictions) then it will fall within the safe harbor of the TTBER. The hard-core restrictions include price fixing, limitations on output, and certain attempts at market or consumer allocation. The excluded restrictions include exclusive grant backs, no challenge clauses, and restrictions on exploiting own technology.

Therefore in addition to understanding the overriding principles of certain jurisdictions, the parties need to draft their collaboration and license agreements in line with obtaining shelter under the TTBER to avoid future litigation. Furthermore, they need to keep abreast of developments in this area as the current TTBER is due to expire on April 30, 2014, and there is an EU consultation in process for a new TTBER.

Bankruptcy Provisions That May Trump Agreement Provisions

The statutory provisions regarding bankruptcy also govern the express intent of the parties memorialized in their collaboration and license agreement. In the United States, a patent license is an executory agreement that may be assumed or rejected in bankruptcy regardless of whether the agreement says it terminates under such circumstances.[20] When the bankrupt entity is the licensor, the statute protects the licensee from losing its license because even if the trustee for the licensor rejects the license agreement, thereby discharging the licensor's future obligations under the agreement, the licensee may elect to retain its license for existing intellectual property granted therein.[21]

When the bankrupt entity is the licensee, there is more variation in the manner in which the states apply the laws with the analysis turning on whether the license agreement will be assigned. The wording in the statute states, in part, that the trustee may not assume or assign any executory contract where such party does not consent to such assumption or assignment.[22] In some jurisdictions, the courts apply a "Hypothetical Test" that considers whether the bankrupt entity could, hypothetically, assign the agreement because the agreement provides consent.[23] If yes, then the agreement may be assumed because it could be assigned regardless of whether or not the agreement actually will be assigned. If not, then the agreement may not be assumed because it could not be assigned regardless of whether or not the agreement actually will be assigned.[24] Other courts apply an "Actual Test" that considers whether the bankrupt licensee actually intends to assign the agreement.[25] If not, assumption is permitted, even if an assignment is prohibited by the agreement because an assignment is not actually occurring.[26] Some jurisdictions are unsettled.

The jurisprudence also varies significantly from jurisdiction to jurisdiction in Europe, and generally there are very few specific provisions under any country's statutory scheme addressing what happens to licensed intellectual property rights on insolvency. The complexity and lack of clarity is due to the fact that these intangible rights are dealt with in much the same way as other types of property rights under national insolvency laws. In Europe, the European Union Regulation on Insolvency[27] determines whose insolvency proceedings apply, regardless of the terms of the collaboration and license agreement. Once, the forum for the proceedings is established then substantive legal differences also may apply. In Germany, for example, the liquidator may elect non-performance of the relevant contract and may then sell the asset to a competitor on the open market. In the United Kingdom, the ability of a licensor to exercise its contractual right to terminate a license in the event of the licensee's insolvency was recently confirmed.[28] This standard contractual right offers a licensor the right to retrieve the rights granted to a licensee if the licensee becomes insolvent. In the reverse scenario of licensor insolvency, the ability of a licensee to safeguard its rights deriving from the license is less straightforward.

Policies in the United States that Trump Agreement Provisions

Public policy in the United States affects the enforcement of license agreements. For example, public policy favors the ability to challenge potentially invalid patents. In the US Supreme Court's decision in *MedImmune*, the Court found that there was a case and controversy sufficient to support a licensee having standing under Article III of the US Constitution to bring a declaratory judgment action to invalidate a patent under which it was licensed, without having to terminate its license. Currently in the United States, covenants barring future challenges to a patent's validity entered into prior to litigation are unenforceable, regardless of whether the agreements containing such covenants are styled as settlement agreements or simply as license agreements.[29]

Conclusion

In this article, we have highlighted a number of considerations affecting the intent of the parties set forth in their collaboration and license agreements. It is vital that parties appreciate the differences that exist outside of their jurisdiction and structure these agreements with the legal landscape in mind based on what can be contractually effective and what cannot. This will help achieve alignment and successful long-term collaboration between the parties.

1. In re CFLC, Inc. v. Everex Systems, Inc., 89 F.3d 673 (9th Cir. 1996).
2. California, Delaware, Illinois, Kansas, Minnesota, North Carolina, Washington, and Utah.
3. Section 39(1) United Kingdom Patents Act 1977.
4. The German Employees' Invention Act (Gesetz über Arbeitnehmererfindungen (ArbnErfG) 1957 (as amended).
5. 35 U.S.C. § 200 (2000).
6. Ethicon v. United States Surgical Corp., 135 F.3d 1456, 1460 (Fed. Cir. 1998).
7. Section 40(1) United Kingdom Patents Act (1977).
8. Kelly & Chiu v. GE Healthcare Ltd., EWHC 181 (2009).
9. Unilever PLC & Others v. Shanks, EWCA Civ 1283 (2010).
10. X c. Société Nationale des Chemins de Fer Français et Vape Rail International SAS (VRI), Tribunal de grande instance of Paris, 3rd chamber, 1st section, May 19, 2009.
11. 35 U.S.C. § 200 (2000).
12. 35 U.S.C. § 204 (2000).
13. Federal Trade Comm'n v. Superior Court Trial Lawyers Ass'n, 493 U.S. 411, 433 (1990).
14. 35 U.S.C. § 271(d)(5) (2011).
15. U.S. Philips Corp. v. ITC, 2005 U.S. App. LEXIS 20202 at *9-10 (Fed. Cir. Sept. 21, 2005); *quoting* Mallinckrodt, Inc. v. Medipart, Inc., 976 F.2d 700, 704 (Fed. Cir. 1992).
16. Brulotte v. Thys Co., 379 U.S. 29, 32 (1964).
17. Transparent-Wrap Machine Corp. v. Stokes & Smith Co., 329 U.S. 637, 645-648 (1947).
18. Federal Trade Comm'n v. Indiana Federation of Dentists, 476 U.S. 447, 458 (1986); *quoting* Chicago Board of Trade v. United States, at 238.
19. Commission Regulation (EC) No. 772/2004 of April 7, 2004, on the application of Article 81(3) of the Treaty to categories of technology transfer agreements.
20. 11 U.S.C. § 365(c) (2005).
21. 11 U.S.C. § 365(n) (2005).
22. 11 U.S.C. § 365(c)(1) (2005).
23. Matter of West Electronics, Inc., 852 F.2d 79, 83 (3d Cir. N.J. 1988).
24. In re Catapult Entertainment, Inc., 165 F.3d 747, 755 (9th Cir. 1999).
25. Institut Pasteur v. Cambridge Biotech Corp., 104 F.3d 489, 493 (1st Cir. 1997); *cert denied*, 521 U.S. 1120 (1997).
26. *Id*.
27. Council Regulation (EC) No. 1346/2000 of May 29, 2000, on Insolvency Proceedings.
28. Perpetual Trustee Co Ltd. et al. v. BBC Worldwide Ltd., et al., EWCA Civ 1160 (2009); WLR (D) 322 (2009).
29. Rates Technology Inc. v. Speakeasy, Inc., Best Buy Co., Inc., Speakeasy Broadband Services, LLC, Megapath, Inc., Covad Communications Company, Covad Communications Group, Inc., CCGI Holding Corporation, Platinum Equity, LLC, 685 F.3d 163, 172 (2d Cir. 2012).