Legal Issues Affecting IP Transactions in Life Sciences

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This article features highlights from a presentation by the authors and Allan Bowie of AJ Park and Son at the LESI 2008 Annual Meeting in which the panel of attorneys shared their perspectives of the legal influences on deal structures and terms in the life sciences in the United States, Europe, Asia, and New Zealand.

United States

US legal issues affecting life science transactions is considered from a chronological perspective: The latest "cutting edge" decision whose consequences are not yet clear; decisions and statutes referred to as "fermentors" that we have been grappling with for a while; and "moldy oldies," or statutes that generally are decades-old but still affect deals in the life sciences.

Cutting Edge

Decided by the US Supreme Court June 9, 2008, *Quanta Computer, Inc. v. LG Electronics, Inc.* [1] addressed the legal doctrines of patent exhaustion and implied license. Patent exhaustion, also known as the first-sale doctrine, holds that all patent rights are exhausted with the first authorized and unconditional sale of product. The patent exhaustion doctrine prohibits patent owners from enforcing their patents against subsequent licensees/purchasers of a previously licensed/purchased product.

The Supreme Court's decision in *Quanta* expanded the scope of the patent exhaustion doctrine to include method claims.[2] In 2006, the Court of Appeals of the Federal Circuit held in *Quanta* that patent exhaustion did not apply to method claims.[3] The Supreme Court disagreed, holding that method claims are exhausted when the product sold embodies substantial features of the patented invention.[4] The question of what does and does not constitute "substantial features of the patented invention" is yet to be resolved.

Based on contract language rather unique to the facts of *Quanta*, the Court of Appeals of the Federal Circuit found that Intel's sale to LG was conditional;[5] to which the Supreme Court disagreed and found an unconditional sale. Quanta's license to Intel required Intel to notify its customers that the customers were not licensed to use the products independently of Intel's products, but it also authorized Intel to make sales and stated expressly that patent exhaustion applied.

Critical to the Court's analysis was the interpretation of these contracts between Quanta and Intel, and the effect the contract language and notices provided along with Intel's sale of microprocessors and chip sets to LG Electronics had under the legal doctrine of implied license. A license will be implied, and prevent the patent owner/licensor from enforcing patents against the purchaser, where there are no non-infringing uses for the product, and the conditions of license/sale evidence the parties' expectation that the product would be used in the infringing manner. An implied license may be rebutted by written notice.

Post-*Quanta*, licensors may be less willing to rely on the language of the traditional grant of "all rights." Licensors likely will favor a narrow and explicit grant with a definition of what constitutes an "authorized sale" under the license and limiting an authorized sale to one in which there is compliance by licensee/purchaser of all the conditions in the license or purchase agreement.

The panel also discussed whether it would be administratively practicable in life science deals for the patent owner to enter into direct agreements with all licensees/purchasers in the chain, or at the very least, be designated as a third party beneficiary in any agreement entered into on its behalf (whether or not it must be expressly so stated to have effect). Regarding the implied license aspect of *Quanta*, written notice to all entities, including subcontractors, sublicensees, and customers, where commercially practicable, is reaffirmed as good practice and necessary to rebut the implied license defense.

Fermentors

Two legal issues of significance in life science transactions over the last few years are: (1) the effect of *MedImmune, Inc. v. Genentech, Inc.*,[6] in which the US Supreme Court held that licensees do not have to terminate or breach their license to have the necessary jurisdictional basis to bring a suit challenging the licensed patents; and (2) statutory and common law research exceptions from infringement.

Post-*MedImmune*, licensors are still including the right to terminate the license if the licensee challenges licensed patents, even though it is uncertain whether such provisions will be enforceable in all jurisdictions. Some licensors have expanded the right to terminate the license if the licensor is sued by the licensee for any reason, on the grounds that the licensor has the right to refuse to remain in contract with a party that has sued it. More detailed blue pencil provisions have been added to clarify through severability the intent of the parties to have the terms enforced in any jurisdiction possible, as well as all other terms that are not invalid or enforceable.

Licensors also are looking for financial deterrents, such as asking for patent validation payments upon successful defense of any challenge, whether by licensee or a third party. The rationale for requesting such payments is that a patent that has withstood challenge is more valuable and the prospect of a validation payment may cause a licensee tempted to challenge the patent to evaluate the difference between the royalties it will pay under the license and the increased cost if its challenge is unsuccessful. There has been an increased use of alternative pricing models that might incentivize licensing rather than infringement, such as lower priced reasonable and non-discriminatory (RAND) licenses, often used in conjunction with licensing standards.

MedImmune has changed the dynamics of negotiating intellectual property transactions. In cases following *MedImmune*, merely showing a preparedness and willingness to enforce rights is enough to sustain declaratory judgment jurisdiction.[7] In particular, sharing claim charts, infringement analyses, or making monetary demands have been held to support a declaratory judgment action.[8] A patent owner's exposure may be limited by use of a non-disclosure/confidentiality agreement that states that the information exchanged will not be used as a basis for bringing a declaratory judgment or other action adverse to the discloser.

Part two of the Fermentors discussion considered the two recognized research exceptions in the United States: (1) a statutory exception to patent infringement for drug development that exempts use of patented subject matter reasonably related to development and submission of information under federal law regulating drugs;[9] and (2) a narrowly drawn common law exception for actions of amusement, to satisfy idle curiosity, for strictly philosophical inquiry, or to ascertain the sufficiency and verify the exactness of an invention.[10]

Given these exceptions, the standard definition of "licensed products" has shifted from products that would infringe, but for the license, to also expressly include products that would infringe, but for the exception in 35 U.S.C. § 271(e)(1), or a similar exception in the United States or other countries. Reciting excepted activity in the definition of licensed products clarifies that the licensed product will still fall within the definition and trigger payment terms, such as regulatory milestones, even if such product also is covered by a research exception. Licensors also are clarifying their continued right to practice, even in exclusive deals, and especially regarding know-how often difficult to disgorge from an employee's head, for internal research purposes or however the licensor defines its internal "legitimate business interests."[11]

Moldy-Oldies

Some of the most pervasive legal influences on life science transactions have been around for decades. The US segment of the panel presentation concluded with a discussion of "Moldy Oldies," statutory provisions that continue to be relevant in life science deals: the Bayh-Dole Act, the US Bankruptcy Code, and the US Department of Justice Antitrust Guidelines.

The Bayh Dole Act[12] permits recipients of research funding from the US Government to elect title to inventions conceived or first actually reduced to practice with federal funding, in exchange for compliance with the act, its regulations, policies, and contracts. The US Government has the right to practice and have practiced on its behalf these inventions. Defining an invention as one "first actually" reduced to practice creates a discrepancy between the act and US patent law, which defines an invention at conception.[13] This discrepancy may be addressed in life science transactions by specifically defining the party's rights in technology first made under a collaboration that also is federally funded, as well as what affect that first actual reduction to practice has on the previously filed patent applications.

The Bayh Dole Act prohibits a non-profit recipient of funding from assigning these inventions, and the intellectual property therefrom. Even when an agreement would purport to make such an assignment, the act will govern. Non-profit recipients are required to give preference to licensees that are small businesses. In the event a major pharmaceutical manufacture desires a license under federally funded inventions, it should ensure the inventions also were offered to licensees that are small businesses. The recipient of this funding must ensure the inventions are substantially manufactured in the United States, unless waived by the Government. Waivers can be time consuming to obtain. A licensee may require the recipient to solicit the waiver prior to executing the license. Understanding these and the other requirements of the Bayh Dole Act aids negotiations for collaborations and licenses of such funded research.

The rights of the non-bankrupt party were considered during the bankruptcy aspect of the Moldy Oldies segment. A license is an executory contract under the US Bankruptcy Code,[14] which means that when the bankrupt party is the licensor, the agreement may be rejected or assumed in bankruptcy, regardless of the language in the agreement. The licensee may treat a rejection of the license as a termination of that agreement, or retain the license under intellectual property then in existence, provided that such licensee complies with the terms of the license, including the payment requirements, and the obligations of the licensor under the license cease.[15] Given these requirements, licensees often request terms in the license to permit the licensee to assume control of prosecution of patent rights and other intellectual property decisions in the event the licensor becomes insolvent.

When the party in bankruptcy is a licensee, the situation is different. The trustee in the bankruptcy proceeding of a debtor licensee may not assume or assign any license absent consent of the licensor when the underlying body of law regarding such rights would prohibit assignment.[16] While applicable law would excuse the licensor from accepting performance other than from the licensee, US courts are split on the interpretation of the Code. Some courts read the statute as preventing assumption by the debtor licensee without the consent of the licensor whether or not the licensee intends to actually assign the license. Other courts consider only whether the license actually will be assigned, and if not, will permit the assumption of the license. Yet a third interpretation asks whether the actor on behalf of the debtor licensee is a "trustee," and if not, does not find the language of the bankruptcy statute applicable to the actions of a non-trustee in assuming the agreement. The variation in interpretations has lead licensors to consider whether an express prohibition on assignment and assumption of the license would be enforced.

The US perspective concluded with a reminder that the Antitrust Guidelines for the Licensing of Intellectual Property, US Department of Justice/Federal Trade Commission, 1995, available at: *http://www. usdoj.gov/atr/public/guidelines,* continue to influence intellectual property transactions in the life sciences.

Europe

There are a number of EU directives and country-specific regulations to consider when engaging in licensing negotiations with an EU-based partner or where key activities under a license will take place in the European Union. Under conflicts of laws principles, also known as *lex loci protectionis,* simply choosing the law of a non-EU country to govern the contractual relationship will not remove the reach of many EU-wide and country-specific provisions, so familiarity of key principles affecting licensing in the European Union is paramount, given the size of the EU market.[17]

When the Parties Cannot Get Along

Even at the term sheet level, the parties need to be mindful of which country's laws will apply, because a breakdown in negotiations at this stage could cause legally enforceable damages against a party who leaves the negotiation table in bad faith. Under the doctrine of *culpa in contrahendo*, which manifests itself in civil law, a duty of good faith in negotiations is implied, and a party who incurs costs on the expectation of closing a deal may be able to recoup those costs against the negotiation partner who backs out.[18] Belgium, Denmark, France, Germany, and Italy are among those countries that subscribe to this principle, whereas the United Kingdom, a common law jurisdiction, does not recognize this doctrine. Thus, if a term sheet does not specify the choice of law governing the parties' negotiations and one of the parties is domiciled in a country where *culpa in contrahendo* applies, one can imagine the possibility for dispute if a party walks away from the negotiation.

Another area in which a choice-of-law clause can be outcome determinative concerns the admission of extrinsic evidence during dispute resolution proceedings when the parties disagree on the meaning of the contract. Whether extrinsic evidence (*e.g.* correspondence during negotiations) can be admitted to interpret the parties' intent depends on the laws governing such disputes. Generally, it is more difficult to admit extrinsic evidence in a common law jurisdiction than in a civil law jurisdiction, because the former countries are steeped in an objective theory of contract, whereas civil law countries largely adhere to a subjective standard.[19] However, it is necessary to consider the laws of the specific country (or state, when dealing with the United States) in light of the

type of contract to appreciate the parameters concerning admission of extrinsic evidence.[20]

Biotech-Specific EU Regulations

There is a series of EU directives (and, correspondingly, national laws of the EU member states) that pertain specifically to life sciences related technology that one needs to remember with dealing with such technology within the European Union. In particular, Directive 2004/23 regulates handling of human tissue and cells; Directive 95/46 regulates protection of personal data; and Directive 98/44 regulates legal protection of biotechnological inventions. Germany and Italy are particularly strict on the use and patenting of certain types of cell lines, such as human embryonic stem cells, although recently Germany has amended its laws on April 11, 2008, permitting the use of even more stem cell lines for research purposes.

Joint Ownership of IP

Defining ownership of collaborative IP can be one of the most hot button issues in a collaboration agreement, especially in the life sciences field in which assessing inventorship is an extremely difficult task. Recognizing this point, many parties rightfully choose *not* to link ownership of collaborative IP to inventorship, to avoid creating an environment that discourages dialogue when the creation of high stakes IP rights is on the line. Many times, though, collaborating parties simply agree, without more, that collaborative IP will be jointly owned omitting to explicitly delineate whether and to what extent the joint owners can exploit the IP.

Notwithstanding a choice-of-law clause, it is likely that the legal effects of joint patent ownership will be decided according to the laws of the country where a particular patent dispute arises, *e.g.,* the laws of Germany will govern a dispute surrounding the exploitation of a German patent, whereas the laws of Italy will govern in the case of an Italian patent. Put simply, the laws of the various EU member states differ with respect to the consent and accounting requirements of joint patent owners, leaving the parties with conflicting sets of rights among the various EU member states,[21] not to mention that the laws of the United States concerning exploitation of jointly owned patent rights are drastically different, giving a joint owner the default right to exploit a patent (whether through licensing or otherwise) without the consent of and without accounting to the other owners.[22] For this reason—and regardless of a sole or joint ownership scheme—parties are encouraged to explicitly address key IP topics such as the right to patent prosecution, sub-licensing, assignment, compensation and right to enforce, including a party's obligation to cooperate with the party enforcing the IP.

Another principle to consider in the area of patent ownership is whether there are any national laws governing how to claim an invention from a company's employees. In Germany, the law concerning employee inventions (*Arbeitnehmererfindungsgesetz*) cannot be avoided when German resident employees conceived of an invention that is the subject of the parties' agreement. This law places certain burdens on the German employer not only to timely claim the invention from a qualifying employee, but also compensate the employee in a manner prescribed under the law. Failure to timely claim the invention will vest title of the employee's share of the invention with the employee, who would not be prohibited from licensing the invention to a third party.[23] Thus, specific attention should be given to the identification and filing of patent rights when collaborating with a German company.

EU Anti-Competition Law Considerations

One of the most important provisions within the European Union that simply cannot be "contracted out of" by a choice-of-law clause concerns EU anti-competition law[24] and, correspondingly, the Technology Transfer Block Exemption Regulations (TTBER). EU anti-competition law will apply to any agreement that has any appreciable effect on trade between EU member states, regardless of the domicile of the contracting parties or the law the parties have chosen to govern the contract, and the TTBER dictate when a license agreement is exempt, *en bloc*, from anti-competition law. Much has been written on the modified TTBER scheme, effective since May 2004, which espouses a "rule of reason" approach akin to the US approach to anti-trust law, so this article does not address the TTBER in great depths. Rather, this article addresses the framework provisions of the TTBER and key implicated clauses affecting licensing within the life sciences industry.

For contracting parties' agreement to be exempt, *en bloc*,from the EU anti-competition regime, there must be, at a minimum, a technology transfer between two undertakings that permits the production of the contract products,[25] and most collaboration agreements between life sciences companies satisfy these requirements. Moreover, the parties to the agreement must stay under certain market share thresholds, although falling outside the TTBER for exceeding the thresholds does not *per se* invalidate the parties' agreement, but instead means the parties must engage in "self assessment" (a rule of reason approach) to determine whether the agreement is, overall, pro-competitive. Even when the parties' agreement satisfies the aforementioned minimum requirements, the parties should be careful to avoid any "excluded" or "hardcore" restrictions in their agreement. Whereas an "excluded" restriction is, itself, removed from the

umbrella of the Block Exemption,[26] a "hardcore" restriction operates to remove the entire agreement from the Block Exemption.[27]

An "excluded" restriction particularly important to a life sciences collaboration agreement concerns access to improvements, given the unique characteristics of "platform" technologies that one of the collaborating parties often brings to the table. On one hand, a licensor who makes its discovery platform available to a licensee does not want the licensee to freely exploit platform improvements that were made under license to the platform; on the other hand, the licensee may be fearful of assigning back to the licensor each and any improvement without knowing what those improvements will be. Under the TTBER, a requirement to exclusively license or assign back to the licensor any improvements that are non-severable (*i.e.* cannot be exploited without infringing the licensor's rights in the platform) is generally an enforceable clause, whereas an exclusive back-license or assignment (as opposed to a mere non-exclusive back-license) with respect to severable improvements may not be enforceable if economic benefits do not outweigh the anti-competitive effects.

One "hardcore" restriction very germane to a drug discovery collaboration relates to post-patent-expiration royalty terms, given long drug development timelines, which can lead to a commercial launch date when "background" patents have limited remaining life. Under the TTBER, a licensor of patent and know-how rights generally can extract royalties even after patent expiration on the basis of know-how that remains secret; a royalty step-down that attributes value to the expired patent rights is recommended.

Concluding Thoughts

Choice-of-Law clauses remain very pivotal, especially when resolving disputes concerning contract interpretation. However, conflicts of laws issues can override a Choice-of-Law clause in numerous situations. Thus, parties to a life sciences collaboration agreement should familiarize themselves with key problematic *lex loci*-relevant provisions affecting the key jurisdictions underlying their license agreement and try to find a "least common denominator" solution across these jurisdictions—pushing the envelope in one jurisdiction could have detrimental spill-over effects. Finally, parties should endeavor to include a well-reasoned "severability" clause, to effectuate the parties' intent as to the remaining provisions, in case a provision is held invalid; otherwise, the entire agreement may become invalidated.

China

There is not a universal law to regulate transfer of technologies (including patents, patent applications, and non-patent technologies) in China. Relevant provisions on transfer of technologies are found spread in many laws and regulations, among others, the Chinese Contract Law, the Chinese Patent Law, Regulations on Technology Import and Export, Regulations on Pharmaceuticals Registration.

Requirements of Transfer of Patents and Technologies under the Chinese Contract Law

The Chinese Contract Law is the main regulatory law for technology transfer, which stipulates some basic requirements for technology transfer contracts. The basic provisions are:

1. A technology transfer contract shall be in a written form. An oral contract for technology transfer may be unenforceable.
2. Only entitled rights such as patents, patent application rights, and technical secret rights are the objects for technology transfer contracts. Those not entitled technologies are not objects of technology transfer contracts. For instance, those technologies, knowledges, experiences, or information that have no relation to patents, patent applications, or technical secrets are not technology transfer objects.
3. Only existing and specific rights are transferable, such as specific patents, patent applications and technical secrets. Those not-presently-existing technologies are not legitimately transferable, for instance, technologies that are still under research and development, technologies that may be possibly developed in the future. In case in an employment contract there provides to transfer all future inventions to an employer may not be legally tenable for or regarded as a technology transfer contract.
4. Under the Chinese Contract Law, the technology transfer contracts are limited to the following four kinds:
   (a) Contract for patent assignment,
   (b) Contract for patent application assignment,
   (c) Contract for technical secret assignment, and
   (d) Contract for patent license.
5. Under the definition of the Law, transfer of technologies comprehends the assignment and license. The assignment applies to transfer of patents, patent applications, and technical secrets. The license applies to transfer of patent rights.

Transfer of the right to apply for a patent refers to the situation to transfer a technology before patent application is filed. The transfer of such a right is essentially the same as transfer of non-patented technology, *i.e.*, technical secrets. Therefore, the transfer of the right to

apply a patent is subject to the provisions for transfer of technical secrets.

Some Special Issues Relating to Technological Transfer Contracts

License Contract of Patent Application

Even though the Contract Law provides that a patent application right shall not be licensed, in practice, it is not unusual to find patent application license contracts. To solve the problem, the Chinese Supreme Court construes in article 29 of its Interpretation of Contract Law, "people's courts shall not hold a contract invalid merely on the ground that the contract established by the interest parties is a license contract for a patent application right of a pending application." "In regard to such a patent application license contract, before the application is published, the regulations on transfer of technical secrets shall be applied; after publication but before grant, it shall be dealt with in reference to the regulations on patent license contract; after grant, it shall be regarded as patent license contract and be regulated likewise."

Transfer of a Patent Right

In transfer of a patent right the transferor (assignor or licensor) shall guarantee the truthfulness and maturity of the relevant patent. He shall guarantee he is the legitimate owner of the patent and the patented technology is intact, flawless, effective, and target-achievable. Under the interpretation of the Supreme Court, the requirement of guarantee of maturity of a patented technology limits the transferable patent technologies to those that are suitable to the production operation, helpful in developing new products, enhancing product quality, reducing operation cost, raising management level, and having economic benefits. Such a requirement for the patented technology is much higher than that of the utility of a patent. The patent utility requirement is a technical possibility of use while the requirement for a transferable patent technology is really of ready industrial or commercial use. Because of that difference, when transferring those technologies that have not been industrially or commercially used, the contract is recommended to clearly provide that the transferred technology is a patent, which might be further developed for industrial or commercial use.

Under the Chinese Contract Law, the transferor does not have the liabilities to provide the assignee or licensee with technical materials and/or technical service. If such technical materials or technical service are needed, they/it should be specifically stipulated in the contract.

Existence of Prior Use

In case a prior use right is found after a license contract has been signed and the existence of the prior use may cause definite losses to the licensee, the licensee may request for a reduction of royalties, but not for termination of the contract.

Interference by another Patent

In case the use of the licensed patent may be interfered with by another prior existing patent, the existing patent becomes an obstacle for implementing the licensed patent. Because use of the licensed patent is preconditioned to obtain an approval to use the prior existing patent from the patentee of that patent, the licensee has the right to request the licensor to remove the obstacle. Licensee is not liable to solve the problem. Optionally, the licensee may directly request termination of the contract.

License of Technical Secrets

Even though the Chinese Contract Law only provides assignment contract as a form, but no license form for transfer of technical secrets, in article 25, section 3 of the Interpretation of Technological Contract, the Supreme Court has construed that the transfer of technical secrets can be in the form of license contract. A license contract for a technical secret could be enacted in reference to the provisions for patent license contract.

Legitimate Restrictions and Illegal Restrictions

As a license contract, it is legitimate to provide certain restrictions of using the technical secret. For example, it could provide the nature of license (*i.e.*, the sole license, exclusive license, or non-exclusive license), the term period, the territory, and the way of using the technical secret (*i.e.*, the manufacture, use, sale, or all the activities). If there is no specific provision on the nature of the license in a contract or the provision is unclear, it shall be regarded as a non-exclusive license. If there is no specific provision for the term period or the provision is unclear, the licensee can use the technical secret forever. If there is no specific provision for territories or the provision is unclear, the licensee can use the technical secret worldwide. If there is no specific provision for the way of use or the provision is unclear, the licensee could enjoy using it in any way.

Again as a license contract, restrictions to the way of using the technical secret shall not go beyond to limit competition or hinder technology development. In article 11 of Interpretation of Contract Law, the Supreme Court stipulates that the following six provisions in a contract exemplify illegal monopolization of technology and obstruction of technology development provided in article 329 of the Chinese Contract Law:

1. To forbid the opponent party to further improve the technology, or to grant-back improved technologies on a unfair or unequal reciprocal basis;

2. To restrict the opponent party to acquire technologies from other resources;
3. To obstruct the licensee from sufficiently utilizing the technology according to the market demand;
4. To coerce the licensee to accept irrelevant tying-in conditions;
5. To unreasonably restrict the licensee from freely selecting other resources to buy raw materials or spare parts or equipments; and
6. To forbid the licensee from challenging the validity of the intellectual property rights of the licensed technology.

Maintenance of Secrecy of Technical Secrets

Expiration of the contract for transfer of technical secrets will not free the relevant party from the liability to keep the technical secret confidential, if the secret is still not disclosed to the public. The liability of keeping secrecy may not forbid the licensor from filing a patent application, unless the contract provides otherwise.

Article 355 of the Contract Law provides that when laws and administrative regulations stipulate otherwise on contracts for technology import or export or on contracts for patent and patent applications, the relevant provisions thereof shall govern.

Requirements for Patent and Technology Transfer under the Patent Law

The Chinese Patent Law contains two articles that relate to patent and patent application transfer. Article 10 provides patent and patent application assignment and article 12 together with its corresponding rule 15 in the Implementing Regulations provides patent license.

The main points of article 10 of the Chinese Patent Law are as follows:

- Patent application rights and patent rights can be assigned;
- The parties shall reach a written contract for the assignment of patent application rights and patent rights;
- The assignment contract shall be registered with State Intellectual Property Office;
- The assignment contract comes into force from the date of registration;
- If a Chinese entity or Chinese individual assigns its or his patent application right or patent right to a foreigner, an approval shall be obtained from the State Intellectual Property Office.

The main points of article 12 of the Chinese Patent Law and rule 15 of its Implementing Regulations are:

- A written license contract shall be reached if any entity or individual wishes to use the patent of others;
- The licensee does not have the right to sublicense a third party to use the patent;
- If the patentee signs a license contract with a relevant party, he shall record the license contract with State Intellectual Property Office or local IP offices.

Most provisions of the Chinese Patent law are the same as provisions in the Chinese Contract Law. The differences lie in that the assignment contract shall be registered with State IP Office and the contract shall come into force from the registration date. The license contracts shall be recorded with State IP Office or local IP offices. To assign a patent or patent application, an approval may be needed for SIPO.

Some Other Issues under the Chinese Patent Law

Registration of Assignment Contracts

Under the Chinese Contract Law, the establishment of a contract is different from the effectiveness of a contract. An established contract may not absolutely mean that it has become effective. If some administrative regulations provide that effectiveness of a contract shall be based on certain formalities, without fulfilling the formalities the contract does not become effective, even though it has been established. Many contractors did not exercise due diligence to register their patent assignment contracts with SIPO. An actual case concerning an unregistered patent assignment contract was heard by a Chinese court. The Chinese court held that the assignment contract had been established because the contract had met all the basic requirements of a contract provided in the Contract Law.

However, because the contract had not been registered with SIPO as required by the Patent Law, the contract had not come into force. So when deciding the liabilities, the judges depended on the faults of enacting the contract rather than on the breech of contract. This case proves that registration of an assignment contract for patents and patent applications are essential.

Recordation of Patent License Contract

Recording a patent license contract is a requirement of the Patent Law. However, failure to record the contract shall not affect its effectiveness. One possible advantage of recording a patent license contract is, if in a patent infringement proceeding, the royalties in the recorded contract may serve a basis for deciding the damages.

Approval for Assignment by SIPO

The Chinese Patent Law provides when a Chinese entity or individual transfers its or his patent right or patent application right to a foreigner, it or he shall get an approval from the State Intellectual Property Office.

Sublicense

Under the Patent Law, the licensee is absolutely excluded from the sublicense. However, under the Supreme Court constructions, a licensee may be allowed to sublicense the technology in certain conditions:

1. If the license contract is a sole license; and
2. If the exclusive licensee is not able to implement the technology.

Technology Transfer under Regulations on Technology Import or Export

The Regulations on Technology Import or Export classifies technologies into three kinds, namely freely import-export technologies, import-export restricted technologies, and import-export prohibited technologies. Formalities requirements are different for different kinds of technologies. For the freely import-export technologies the formality is to record the technology transfer contract with the Ministry of Commerce. For import-export restricted technologies the formality is to request for an approval from the Ministry of Commerce.

In addition to the provisions in the Chinese Patent Law, the Regulations on Technology Import or Export provides that when a Chinese entity or individual transfers its or his technology to a foreigner, it or he shall go through the regulatory formalities provided in the Regulations. If the technology is one restricted by the Regulations, the transferor shall get approval from the Ministry of Commerce before actually assigning the technology to foreigners. The technologies referred to in the Regulations include patents and patent applications. Therefore, when Chinese entities or individuals transfer their technologies to foreign parties, double approvals shall be obtained, one from SIPO, the other from the Ministry of Commerce.

For technology that is freely import or export, recordation is required with the Ministry of Commerce. If the technology is a patent both registration and recordation formalities shall be fulfilled, one with SIPO, the other with the Ministry of Commerce.

However, registration has a different legal effect from that of recordation. Recordation shall not affect the effectiveness of a contract while registration is a condition for the effectiveness of a contract.

Technology Transfer under Regulations on Medicine Registration

Many biological technologies relate to pharmaceuticals. Transfer of pharmaceutical-related technologies may additionally be regulated by the Regulations on Medicine Registration. The Regulations provide for two transferable technologies: (1) new drug technology and (2) drug manufacture technology.

There are some special qualification and capability requirements to the assignors and assignees in the pharmaceutical-related technology transactions. To assign a new drug technology the assignor first shall obtain a new drug certificate from the State Food and Drug Administration (SFDA). The assignee of the new drug technology transfer shall be a pharmaceutical production enterprise and hold a GMP recognition certificate. Furthermore, the scope of the assignee's production license and GMP recognition certificate shall be in line with the transferred drug.

To assign drug manufacture technology the assignor shall be a pharmaceutical production enterprise with a pharmaceutical production license and the assignee shall possess a pharmaceutical production license and GMP recognition certificate, the scope of which shall be in line with the transferred manufacture technology.

Transfer of pharmaceutical-related technologies is subject to the examination and approval by SFDA. SFDA makes full examination of applications for technology transfer pertaining to new drug and drug manufacture production. In the following circumstances SFDA shall not approve the transfer:

- The assignor's legal entity registration has expired;
- The drug production license or GMP recognition certificate of either the assignor or assignee has been invalid or cancelled;
- The name of the assignor is different from the one on the new drug certificate and the assignor can not furnish evidence to justify the difference;
- The monitoring period of the new drug has expired;
- The pharmaceutical production license of the assignor has been cancelled or abandoned;
- It is found that a grave potential risk exists in assignment of the intend-to-assign drug;
- The SFDA believes that the assignment of a new drug or drug manufacture technologies shall gravely threaten the pharmaceutical's quality and safety; and
- In some other situations, SFDA believes that the new drug or drug manufacture technologies shall not be allowed to assign.

Biological technologies are very special in technology but have many issues in common in transaction.

Therefore, in procurement of biological patent, many special requirements must be abided by. In transfer of biological patents or technologies all the general requirements of a contract provided in laws and administrative regulations shall apply. In addition, because biological inventions are often in the field of pharmaceuticals the special regulations on the transfer of pharmaceutical technologies will specially govern the bio-tech transfer.

1. Quanta Computer, Inc. v. LG Electronics, Inc., 128 S. Ct. 2109 (2008).
2. *Id*. at 2118 (rejecting the argument that "method claims, as a category, are never exhaustible").
3. LG Electronics, Inc. v. Bizcom Electronics, Inc., 453 F.3d 1364, 1370 (Fed. Cir. 2006).
4. *Quanta Computer*, 128 S. Ct. at 2122.
5. *LG Electronics*, 453 F.3d at 1370.
6. MedImmune, Inc. v. Genentech, Inc., 127 S. Ct. 764 (2007).
7. *See* SanDisk Corp. v. STMicroelectronics, Inc., 480 F.3d 1372 (Fed. Cir. 2007).
8. See *id*.; Sony Electronics, Inc. v. Guardian Media Technologies, Ltd., 497 F.3d 1271 (Fed. Cir. 2007).
9. 35 U.S.C. § 271(e)(1), Hatch-Waxman Act of 1984.
10. *See* Madey v. Duke Univ., 307 F.3d 1351 (Fed. Cir. 2002); Whittemore v. Cutter, 29 F. Cas. 1120 (C.C. Mass. 1813); Sawin v. Guild. 21 F. Cas. 554 (C.C. Mass. 1813).
11. *Id*.
12. 35 U.S.C. § 200 et al., 37 C.F.R. Part 400.
13. 35 U.S.C. § 101.
14. 11 U.S.C. § 365.
15. 11 U.S.C. § 365(n).
16. 35 U.S.C. § 365(o).
17. The following set of topics is by no means an exhaustive list of points to consider from an EU perspective, but reflects the highlights of the panel discussion in Chicago.
18. *See, e.g*., German Civil Code (BGB) § 311(2).
19. Zeller, Bruno, "The Parol Evidence Rule and the CISG [1]—A Comparative Analysis," Working Paper, Pace Law School, New York, USA (2003).
20. In England, extrinsic evidence is generally not admitted except for purposes of contract reformation (G. H. Treitel, The Law of Contract, 192 (11th ed. 2003)), whereas French and German law generally do not limit the admissibility of relevant external materials in the process of interpretation (Vogenauer, Interpretation of Contracts: Concluding Comparative Observations. Oxford Legal Studies Research Paper No. 7/2007 Available at SSRN: http://ssrn.com/abstract=984074). Across the Atlantic, the majority of US states require an ambiguity within the contract itself to admit extrinsic evidence, although California law allows extrinsic evidence to show there is an ambiguity in an otherwise seemingly clear contract (see, e.g., Pacific Gas & Elec. Co. v. G. W. Thomas Drayage Co., 69 Cal. 2d 33 (1968)).
21. *See, e.g*., Feldges & Kramer, Journal of Intellectual Property Law & Practice 2007 2(11):742-749; *http://www.ipr-helpdesk.org/docs/docs.EN/JointOwnership.html*.
22. Ethicon v. U.S. Surgical Corp., 135 F.3d 1456 (Fed. Cir. 1998).
23. For a general overview, see Deck & Matthes, *IAM Magazine*, June/July 2005:63-67.
24. Article 81 of the Treaty Establishing the European Community (Art. 81).
25. Art. 2, paragraph 1, TTBER.
26. Arts. 5, TTBER.
27. Arts. 4, TTBER.

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