How does your licence agreement address timely issues?

Licensing deals are negotiated and licensing agreements written in real time. A robust pro forma licence agreement can save hours of transaction time at critical points in a deal

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Given the pressing need to execute agreements, licensing professionals may find themselves triaging a seemingly endless number of hypothetical eventualities, assessing risk and reward, determining probabilities for success and balancing competing interests of the various stakeholders at a moment's notice. In the throes of a deal, there is often little time to analyse case law or contemplate its effect on key transaction terms.

The best time to contemplate changes to licensing terms is outside the constraints of a specific deal. Critically analysing issues and developing a robust pro forma licence agreement can save hours of transaction time at critical points in a deal. It is also useful to revisit the pro forma periodically to incorporate lessons learned from practice and from the latest case law, and to re-evaluate whether the provisions clearly and concisely achieve your goals.

With this in mind, you may wish to consider how your licence agreement addresses the following issues.

Clearly state what sales are authorised and how they are conditioned

The Supreme Court addressed the legal doctrines of patent exhaustion and implied licence in *Quanta Computer, Inc v LG Electronics, Inc*, 128 S Ct 2109 (2008). Patent exhaustion, also known as the first-sale doctrine, holds that all patent rights are exhausted with the first authorised and unconditional sale of a product. The patent exhaustion doctrine prohibits patent owners from enforcing their patents against subsequent purchasers of a previously licensed/purchased product. The Supreme Court's decision in *Quanta* made it clear that patent exhaustion applies to method claims when the product sold embodies the "substantial features of the patented invention". It is not clear what constitutes substantial features and how an authorised sale must be conditioned to prevent exhaustion.

While we await more guidance from courts interpreting *Quanta*, a tightly worded licence grant is essential, limiting the conditions under which sales are authorised (eg, field of use) and contingent on the licensee's compliance with those limitations. A negative covenant should add clarity if the authorisation and conditions are interpreted.

Licensee agrees that it is not authorised and will not practise or have practised any patents of licensor other than the patent rights listed in Exhibit A, and only in compliance with the terms and conditions of this Agreement. Any conveyance of the patent rights, including subcontracts, sublicences, assignments and transfers, shall be consistent with the terms of this Agreement or shall be null and void. If the licensed products embody the essential features of patents not included in the patent rights, and licensor's rights in such patents are exhausted, then licensee shall indemnify licensor for all loss, including of value, use and direct damages attributable thereto, and pay an additional royalty on all transfer of licensed products, which royalty shall be promptly negotiated by the parties *and not less than the highest royalty rate set forth herein.*

Sufficient reservation of rights

The reservation of rights clause usually allows continued research collaborations with others, especially where government funds were used, but may not be clear on what "research" means. More non-profit institutions, especially hospitals, are seeking investigator-sponsored Investigational New Drug applications and may want reserved rights for clinical trials. Also, inventors may leave the licensor institution and continue their research at another institution, even a company. Addressing these issues during the negotiation should prevent misunderstandings in the implementation process. Consider the following as a starting point:

Licensor reserves: (a) all rights, titles and interests not expressly granted [in the grant of rights section]; and (b) the right to practise, have practised and transfer the subject matter claimed in the patent rights and the technical information for [non-profit] research and development purposes, [including clinical trials] and to publish thereon.

"Licensed products" are defined to include research exempt activity

The definition of "infringement" in the United States includes an exception for uses reasonably related to the development and submission of information under a federal law which regulates the manufacture, use or sale of drugs or veterinary biological products. Laws in many foreign countries have a similar exception. If the licence agreement defines "licensed products" as products or processes that infringe a claim of the patent rights, the definition may unintentionally narrow what triggers payments. For instance, if the licence agreement includes milestone payments based on activities that are technically exempt from infringement (eg, filing an Investigational New Drug application), a broader definition of "licensed products" that expressly includes the otherwise exempt activity will clarify that such activity is within the scope of the rights covered.

"Licensed Product(s)" means any product or process that is covered by a pending or issued and unexpired claim of the patent rights, infringes a claim of the patent rights, or would infringe a claim of the patent rights but for the exception in 35 USC §271(e)(1) or similar exception in the United States or other countries.

First actual reduction to practice results in government rights

Under its retained rights, a university might use federal funding to first actually reduce to practice an invention that was not conceived with government funding. According to the Bayh-Dole Act (35 USC §§ 200 *et seq*), the government's rights attach at such first actual reduction to practice and the university is thereafter required to comply with the Act, including requiring substantial manufacture of the invention in the United States. If the original invention was not federally funded, the licence agreement may not contain the appropriate terms to address Bayh-Dole compliance. To prevent oversights from occurring, all licence agreements could contain language such as the following:

Licensee understands that the patent rights may have been or may be in the future conceived or first actually reduced to practice with funding from the United States government. All rights granted shall be limited by and subject to the rights of the United States government, and licensee agrees to comply and enable licensor to comply with all obligations to the United States government, including those set forth in 35 USC §200 et seq, including substantial manufacture of Licensed Products and products produced through the use of Licensed Products in the United States.

No waiver of sovereign immunity

Licence agreements often include forum selection clauses similar to the language in the licence agreement litigated in *Baum Research and Development Company, Inc v Univ of Mass at Lowell* (Fed Cir 2007): "This Agreement will be construed, interpreted and applied according to the laws of the State of Michigan and all parties agree to proper venue and hereby submit to the jurisdiction in the appropriate State or Federal Courts of Record sitting in the State of Michigan." Baum sued the university in federal district court for breach of contract and patent infringement. The university moved to dismiss the complaint on the grounds that it was immune from suit based on the Eleventh Amendment of the US Constitution. The Federal Circuit affirmed the district court's denial of the university's motion and upheld the ruling that any immunity if the university was waived by the jurisdictional provision of the licence agreement.

Some public universities have responded by no longer including forum selection clauses in their licence agreements. However, it would be helpful to have one, for example in international transactions,

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provided that sovereign immunity is not waived. Consider a provision such as the following to express that intent:

Any litigation or arbitration rising out of or relating to this Agreement that is not barred by sovereign immunity shall be conducted by a court of competent jurisdiction in [insert]. Licensee agrees to avail itself of such courts. Nothing herein shall be construed as a waiver of sovereign immunity by licensor.

Reliance on licensee's recommendations on patent scope

Licensors know the hazard of turning over control of the patent management to the licensee. Even when the licensor retains control of the patent management, advice and comments from the licensee can strongly influence the patent strategy. This is especially true when the licensee has the right to stop funding costs on a patent-by-patent basis.

However, the parties may be motivated by different factors. There may be sound business reasons why a licensee is interested in having the patent rights narrowed or abandoned. For example, the product may be well protected by patents issued to the licensee or licensed from a third party at a lower royalty rate. Consider requiring the licensee to continue to be obligated to pay a lesser amount (eg, equal to the know-how royalty rate or a fraction of the original royalty rate) if the licensee continues to sell licensed products within the territory or scope of the patent rights that the licensee elected to have abandoned or narrowed.

Consequence if licensee sues you

Many are watching how the case law develops to determine the enforceability of provisions that attempt to rebalance the effect of *MedImmune, Inc v Genentech, Inc*, 127 S Ct 764 (2007), where the Supreme Court held that a licensee need not first terminate or breach its licence in order to have the necessary jurisdictional basis to bring a suit challenging the licensed patents. Given the uncertainty of enforceability, consider a layered approach combining provision-specific protections with an enhanced severability clause:

- Create financial disincentives for potential challenges: Use financial terms that redistribute payments earlier in the deal lifecycle; compensate the licensor in the event of an unsuccessful challenge to the patent (by anyone); clarify that all payments are non-refundable and that no amounts shall be paid into escrow.
- Narrow the scope: Convert an exclusive licence to a non-exclusive licence in the event that a licensee challenges the patents in any manner, including opposition or provoking an interference or re-examination.
- Make sure your confidential information is not used as a weapon. Clarify that the permitted use of confidential information shared by the licensor does not include any use that is detrimental to the licensor, including its patent rights.
- Require notice and a meeting: As a material term to the agreement, require that the licensee provide at least 90 days' written notice prior to bringing any challenge to the validity or enforceability of any of the patent rights, and agree to meet at the licensor's offices, to negotiate a solution in good faith that avoids litigation. Consider a special dispute resolution procedure for this issue.
- Knowledge: Include a statement by the licensee that it is unaware of any prior art or other disclosures or activities that would invalidate the patent rights or render them unenforceable. The licensor will likely be asked to make a similar representation. Consider requiring that the parties share any information later learned during the life of the agreement regarding this issue.
- Reimbursement for defending the patent rights: Typically the agreement requires the licensee to reimburse the licensor for filing, prosecution, maintenance and defence of the patent rights. Clarify that this provision includes challenges or other actions brought by anyone.
- No agreements with entities that sue you: Some institutions have a general policy, similar to the "debarment list" used by the government, of not doing deals with people that sue them. This concept could be expanded expressly to include challenges to the patent rights, although the enforceability of such a clause is uncertain.
- Enhanced severability: Include a severability provision that not only requires that effect be given to all valid and enforceable provisions, even if those same provisions are invalid in another jurisdiction, but also requires reformation where possible to effectuate the intent of the parties as evidenced when the agreement was signed.

Change of control

The capabilities and resources of the licensee affect the consideration that the licensor is willing to accept. For example, an inventor-driven start-up company is unlikely to have the same terms in its licence agreement as an out-licence to a Fortune 500 company. With respect to the financial terms of the agreement, equity may have been provided instead of cash upfront and milestones may be more modest. The deal may or may not be structured with an expectation of sub-licensing. Diligence terms may reflect a concession to limited resources through a longer development schedule and lower minimums might have been agreeable at execution.

Fast forward to a change of control of the licensee; if the terms of the agreement are not favourable to the new owner of the licensee, the licensor may be asked to renegotiate. Often this request is accommodated. On the other hand, licence agreements rarely permit or obligate the parties to renegotiate in the event that the licensor would be disadvantaged by a change of control. Consider including provisions in the agreement that address realigning the financial terms to the then-current fair market value, re-evaluating sub-licensing structure, heightened diligence and reversion of patent control to the licensor (if the licensor turns over control to the licensee).

"Small" is not the same

The definition of a "small entity" for patent purposes is not the same as the definition of "small business firm" for Bayh-Dole compliance. Often these terms are mistakenly used interchangeably.

The licensor, often a "small entity", needs to know whether the licensee qualifies as a small entity (defined in 37 CFR §1.27(a)) eligible for reduced patent fees pursuant to 13 CFR §121.802. This is more than a financial concern because incorrectly representing entity status may invalidate the patent.

The Bayh-Dole Act requires annual utilisation reports that include a statement on whether each licensee is a "small business firm". The Bayh-Dole Act has two definitions for the term: one that applies to the act as a whole (37 CFR §401.2(g)) and one particular to the standard patent rights clauses that apply to utilisation reports (37 CFR §401.14(a)(5)). Both Bayh-Dole definitions state that a small business firm is defined by 15 USC §632, and the implementing regulations of the Administrator of the Small Business Administration. The clauses do refer to different parts of the CFR in order to determine "size", but each appears to defer to the individual granting agency's determination of size, which may be amended on a contract-by-contract basis.

Given the annual requirement to report to the funding agency under the Bayh-Dole Act and the issues that could arise regarding small entity status for patent purposes, the licence agreement might require that each licensee certify annually (on behalf of itself, any sub-licensees and any others to which the licensee conveyed the licensed rights), whether or not it qualifies for "small entity" status under 13 CFR §121.802 for patent purposes, and is a "small business firm" under the Bayh-Dole Act.

Conclusion

Licensing deals are negotiated, and the agreements that memorialise them written, in real time. While pro forma agreements have many hazards and need to be used with care, advance preparation of pro forma terms can help you to make quick, informed decisions about key aspects of your deals.

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