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# *Patent and Know-How Licensing—An Insider's Guide*


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Negotiating a patent and know-how licence can be a time-consuming and costly exercise for many businesses. Given the long-term nature of these agreements and the likely significance to the business, it is important to get it right. We therefore explore how parties negotiating these licensing deals can navigate some of the key legal and commercial issues that typically arise and strike an acceptable balance of risk and reward.

We focus on: (i) the importance of defining the deal at an early stage and agreeing headline commercial terms; (ii) assignment and sublicensing considerations; (iii) payment provisions and common pitfalls; (iv) warranties and indemnities; (v) termination; and (vi) dispute resolution mechanisms and strategies when things unfortunately go wrong.

## Part 1—Defining the Deal:

### Why is it important to agree headline commercial points early on?

It will not always be possible to predict the legal and commercial issues that will arise during negotiations. However, there are certain points that will always come up, so taking the time to consider these headline issues at the outset of the commercial discussions (and prior to incurring the time and cost of drafting a complex licence) can be highly beneficial.

We summaries these key headline points below and explain how 'defining the deal' early on can set the right tone for a successful contract negotiation:

- **Due diligence:** From the licensee's perspective, it will want to make sure that the party it is taking a licence from is in fact in a position to grant the rights it needs to exploit the technology. For example, this might include ensuring that any patents are registered in the name of the licensor company (as opposed to another affiliate entity, or a previous owner) and that there are no ongoing legal proceedings that could undermine the value of the licensed technology. Addressing these issues at the outset of the discussions will ensure there are no unwelcome surprises further down the line.
- **Licence Scope:** One of the critical negotiation points will be agreeing the scope of the licence, namely: (i) whether it will be exclusive, non-exclusive, or sole; (ii) any field of use restrictions imposed on the licensee (*e.g.*, for specific therapeutic applications); and (iii) the geographical scope of the rights granted. From the licensor's point of view, it needs to carefully consider the impact on its wider business and future exploitation plans, as granting unduly wide rights could impact the ability to licence its technology to other third parties in the future, or its own commercial activities.
- **Financial terms:** As we explain further below, there are a number of ways in which the financial obligations in a patent and know-how licence

could be structured. This will be a critical element of the commercial deal and it is important that the parties are aligned on agreed royalty percentages, signature fees, and/or milestone fees before spending time and cost negotiating a complex legal agreement.

- **Improvements:** A patent and know-how licence may last for many years, during which time the technology may significantly evolve. This may be the result of improvements generated by the licensee's use of the technology, or the licensor may itself develop new technology that is relevant and useful to the licensee. There are competition law constraints on provisions which require the licensee to grant an exclusive licence or to assign rights in its improvements, so care needs to be taken when negotiating these points. However, thinking about how access to future improvements will be addressed in the licence agreement (for example, by including a contractual mechanism requiring disclosure of the improvement and to have good faith negotiations on the commercial terms) will help to pre-empt future misunderstandings and disputes.
- **Sublicensing:** The ability to sublicence the right to use the patents and know-how may be critical to the licensee's business model, particularly if it does not have the capability or resources to do its own manufacturing. Ensuring these discussions take place at the outset of the negotiations will therefore ensure the licensee understands the boundaries of its sublicensing rights (if any) and how this may impact the feasibility to proceed with the deal.

### So, how do you approach agreeing these headline points in practice?

There is of course a danger of spending a disproportionate amount of time negotiating detailed "heads of terms", which are likely to be non-binding in nature (for the most part) and may ultimately be superseded by subsequent contractual negotiations. However, there is certainly value in having commercially driven, honest discussions to agree (at least in principle) on the key terms outlined above prior to drafting the licence agreement, in order to flush out any deal-breaking issues at an early stage.

While agreeing these high-level commercial points at the outset will help to focus minds, there is of course no guarantee that the subsequent contractual negotiations will all be plain sailing. The guidance set out further below therefore explores the ways in which the parties may look to resolve these complex legal issues.

## Part 2—Maintaining Control: Assignment and Sublicensing

A common challenge in licence negotiations is striking the right balance between: (i) protecting the patents and know-how being licensed by restricting assignment and sublicensing rights; and (ii) allowing the licensee the commercial freedom it needs to successfully exploit the technology being licensed.

### How could the parties address the licensee's ability to assign/transfer its rights under the licence to third parties?

If the value of a licensor's business is based heavily around its IP portfolio, there will inevitably be sensitivity around allowing this valuable technology to fall into the hands of its competitors or to entities that may otherwise raise red flags (for example, due to reputational or financial concerns). For this reason, it is common to impose some level of control as to the licensee's ability to freely assign the licence and the right to access the technology. This is particularly relevant where highly sensitive know-how is being licensed, as giving the licensee an unfettered right to transfer this know-how and associated contractual rights to a third party essentially removes the licensor's ability to carry out appropriate due diligence checks on the incoming party.

These issues do however need to be considered alongside the commercial reality that many licensees will want some flexibility to sell the business assets in the future without the risk of losing critical contracts. This is particularly the case in the pharmaceutical industry, where smaller start-up businesses (or their assets) are regularly acquired by larger pharmaceutical companies once they reach a certain stage in development. Accordingly, requiring permission to assign the licence agreement could create obstacles to this sale process and it will not be in the licensor's interest to impede the commercialization of the technology.

To strike a compromise, a potential solution may be to provide that any consent to an assignment or transfer should not be unreasonably withheld, conditioned, or delayed. While this will not fully allay the licensee's concerns, it ensures that the licensor can only refuse its consent where reasonable to do so (or otherwise risk being in breach of contract by

refusing without justification). Alternatively, the parties may go further than this and pre-approve certain permitted assignments, such as named third parties or group companies.

### What would the parties be considering when negotiating sublicensing rights?

Similar considerations will apply as with assignment and transfers, as the licensor will want to impose robust controls to safeguard its IP. Typically, a licensor would seek prior consent to sublicensing of its technology, which would allow it to assess any material risks associated with the proposed sublicence (*e.g.*, due to jurisdictional concerns in territories where it may be more difficult to enforce and protect confidential information, or where the proposed sublicensee has a history of IP infringement). These concerns are likely to be heightened where know-how or proprietary materials need to be transferred in conjunction with the sublicence, as there is no direct contractual relationship to control the use of such IP.

If sublicensing is to be permitted, other common controls would include: (i) ensuring the licensee takes responsibility for any acts/omissions; (ii) ensuring any materials or information is returned or destroyed at the end of the sublicence relationship; and (iii) requiring the licensee to flow down the relevant contractual terms and conditions in the sublicence agreement.

Again, as with assignment, a lack of contractual freedom may impede the licensee's commercial activities and ultimately act as an obstacle to successfully exploiting the technology. This is particularly the case for smaller early-stage companies with limited resources that need to outsource manufacturing or to collaborate with more established business partners to commercialize a product. For this reason, it would be reasonable to expect certain contractual rights to sublicence the technology, even if subject to strict conditions as outlined above. Where a licensee has specific collaboration partners or manufacturing companies in mind, it may also request advance contractual assurances that these companies will be approved for sublicensing purposes, as this will enable the licensee to strike other commercial deals in parallel to the licence.

### What about change of control situations?

The parties will also want to consider the implications of a "change of control" scenario, as while the contractual parties to the licence may remain the same (unlike in assignment situations), the ownership and operational structure and personnel running the business may change significantly and impact the longer-term relationship. This may occur when a smaller start-up company sells the controlling shareholding in the business to a more established player in the market, which could be a competitor of the other party to the licence agreement.

From a licensor's perspective, the main way to protect against these situations is to include a termination right when there is a "change of control" trigger. However, this is often a sensitive issue in negotiations, as a licensee will be reluctant to accept any restrictions that may hinder its ability to sell and grow the business. These termination provisions will be a significant red flag for prospective investors in any due diligence exercise, as it could result in a critical licence agreement being taken away following a share acquisition.

If a licensor has specific concerns about ownership changes of its licensees, a possible solution might be to confine any potential termination right to a change of control in favor of specific third parties, or defined categories of businesses.

## Part 3—Payment Terms and Common Pitfalls

The payment terms will be a critical part of any licence agreement, as this goes to the heart of the commercial deal and essentially represents the trade-off for being able to use and exploit the licensed technology.

### What are the key negotiation points when it comes to royalty payments?

Once the headline royalty percentages have been agreed at a commercial level (as discussed above), other points to bear in mind include:

- **Defining net sales:** This is essentially the "pot" from which royalty payments will normally be applied, so it is important to understand what this means from an accounting perspective and what can and cannot be deducted from gross sales. A licensor will of course want to minimize these permitted deductions, as this will otherwise have a significant knock-on impact on the amount it ultimately receives. However, it is typical to allow a licensee to deduct applicable tariffs, taxes and customs duties, discounts granted to customers, and other similar provisions.

- **Audit rights:** Given that royalties are typically calculated from the licensee's own sales data, there needs to be a certain level of trust in this accounting process, as a licensor will not necessarily want to spend time and cost scrutinizing every royalty report. However, to protect itself from situations where there is concern over the level of royalties being paid (for example, due to divergence with publicly available sales data), it will be important to include an audit mechanism in the licence. This would grant certain rights to the licensor to inspect and audit the licensee's accounts, subject to certain conditions to ensure a licensee is not constantly being challenged (*i.e.*, by limiting the frequency of auditing), that the auditor is acting independently, and that the costs are appropriately apportioned.
- **Royalty stacking:** Where getting a product to market requires multiple licences, a licensee may attempt to including royalty stacking provisions, to ensure that royalties paid to third parties can be deducted from the figure on which net sales is calculated. However, this may significantly reduce the royalty revenue, so where any such royalty stacking is agreed the licensor is likely to require a royalty "floor" or minimum payment at the very least.
- **Scope of licensed products:** The definition of the "licensed products" will be critical in setting the boundaries of the licensee's royalty obligations and it is common to link this to "valid claims" of the patents being licensed. While a party may be willing to take a licence under a patent with questionable validity in order to avoid an infringement claim and the expense of litigation, it will be at a competitive disadvantage if obliged to continue paying after invalidity has been finally established. For this reason, a licensee would want to include valid claim provisions to ensure that royalties are only payable (at least at the full rate) on products that would otherwise infringe a valid claim.

There is of course a compromise to be struck on many of these complex issues and it is a question of balancing risk and reward.

## What other types of payment obligations might you expect to see?

In some situations, it may be a fairly simple case of charging a fixed royalty percentage based on future sales of licensed products. However, there is often more complexity, as a licensor may not want to rely solely on unknown future royalty income that is dependent on the success of the licensee's commercial activities. On the other hand, where a licence agreement is taken out by an early-stage company with limited financial resources, its ability to fund the licence fees may be solely dependent on the success of the project and seeking further investment. The economic agreement will also be impacted by whether the licence is exclusive or non-exclusive.

To address these competing objectives, one possible solution may be to include certain "milestone fees", where payment is conditional on achieving trigger events. For example, this could require payment of a fixed sum to the licensor on achieving certain financial sales targets, or in the pharmaceutical industry there may be an obligation to pay fixed fees on commencing different stages of clinical trials, obtaining regulatory approvals, and/or on first commercial sale. Ideally, a licensor will also want to charge some form of signature fee or technology access fee at the outset of the contractual relationship (the level of which may depend on whether or not the licence is exclusive). This helps to offset the risk of not receiving substantial royalty revenue further down the line and ensures the licensor is compensated in the meantime. This may be particularly important if there is a limited term remaining on the patents and it could take many years for the licensed products to reach the market.

In addition to these more typical payment structures, parties often find other creative ways of structuring licensing deals. For instance, there may be incentives or reduced payments where a licensee brings other business to the licensor (such as a contact for manufacturing work), which can be mutually beneficial. Similarly, there might be an option for the licensee to "buy out" its future royalty obligations in exchange for an advanced lump-sum payment. This does however need careful thought and a licensor will want to ensure this buy-out is pitched at the right level, as it may otherwise lose out significantly compared to the future royalty revenue for a successful product.

## How long will the payment obligations last?

This will often depend on the nature of the IP included in the licence. If the agreement only includes patents, then a licensee would generally expect to cease paying royalties once all valid claims have expired. However, where the licence includes a bundled package of patents and know-how, as is often the case, there may be a legitimate expectation for certain

financial obligations to continue even following patent expiry. However, it is typical to see a "step-down" in the level of royalties attributable to the use of know-how and a licensee will similarly want to avoid making further payments in circumstances where all of the know-how is in the public domain.

To create certainty for both parties, it may therefore be preferable to include a fixed duration for the royalty term, often by reference to a set number of years following the first sale of a licensed product (if this is later than the patent term). However, a licensor may be pushing for this fixed royalty term to apply separately in each country of sale, as otherwise it could lose out significantly in circumstances where sales in certain major markets do not commence until much later and it only benefits from a relatively short duration of royalty revenue in that territory.

## Part 4—Warranties, Indemnities, and Liabilities

A licensor and licensee will have differing objectives and expectations when it comes to negotiating warranties, indemnities, and liability provisions in a licence agreement. A licensor would be well advised to resist giving any contractual warranties (and associated indemnities) guaranteeing the validity of patents or that the licensed technology will not infringe the rights of any third parties, as these matters are not fully within its knowledge or control. However, a balance can often be struck by qualifying statements by reference to actual knowledge or building in appropriate exclusions from liability. Thinking about the practical risks to the business and how these risks can be mitigated helps to guide decision making on these issues.

It is important to have some pragmatism when negotiating these provisions and to recognize that there will often need to be concessions from each party's ideal contractual position in order to strike an acceptable deal. It also helps to adopt a starting position in a draft licence that is not entirely weighted in one party's favor, as otherwise this will ultimately create more work when it comes to negotiations.

## Part 5—Termination

Terminating a contract is not always the easiest topic of conversation at the outset of a new and exciting commercial relationship. However, failing to consider the potential consequences of a relationship breakdown can have significant implications further down the line.

### What will a licensee's main priorities be here?

A key concern for a licensee will be ensuring that it is not "locked in" to a long-term licence agreement and has the ability to terminate upon giving reasonable notice if, for example, the licensed technology does not work as envisaged and it is not feasible to continue with the project. However, it will not want to grant a reciprocal right allowing the licensor to terminate at any time without cause, as it may have invested significant resources in developing and marketing products and needs some security that the business-critical licence will not be unilaterally revoked at any time.

### And what will be the key concerns for the licensor?

The primary concern for a licensor will be ensuring that there is a clear termination mechanism where the licensee's actions (or threatened actions) may jeopardize the licensed technology. For example, if a licensee fails to pass on appropriate restrictions to sublicensees or commences activities which falls outside the permitted scope of the licence and could impact its other licensees, this may result in a loss of trust in the relationship and force the licensor to take remedial action. Depending on the nature of the breach, this mechanism would typically require a remedy period prior to exercising a formal termination right, in order to give the licensee a final opportunity to resolve its actions.

Termination may not always be the preferred remedy for a licensor, as ultimately this will end the relationship and any prospect of future licence revenue. Accordingly, where royalties or other fees have not been paid, it may be that claiming damages for breach of contract and recovering the sums owed is a more desirable path to take; particularly if there is a bona fide dispute over contractual payment obligations that cannot be resolved, but this does not result in a complete breakdown in the overall commercial relationship. However, a repeated failure to pay fees and royalties may leave a licensor with no option but to trigger termination, particularly if maintaining an exclusive contractual relationship would prevent or hinder it from monetizing the technology through other channels.

As mentioned above, termination for a change of control will be another factor to consider in contract negotiations where there is sensitivity about the technology falling into the hands of certain third parties.

## How do parties grapple with the issue of validity challenges to the licensed IP?

A licensor may also wish to include a right to terminate if the licensee challenges the validity of the patents or contests the secret or substantial nature of the licensed know-how. This is because the licensee is likely to have an intimate knowledge of the technology via the licence relationship and (unless it is an exclusive licensee) it will normally have the strongest incentive to challenge the validity of the IP and be released from further payment obligations and other restrictions.

There are, however, certain competition law rules which set the boundaries of these rights. Under the EU Block Exemption[1] (which forms part of retained EU law in the UK following the Brexit transition period), an absolute ban on challenging the validity of the licensed patents is likely to be unenforceable and will not benefit from the protection of the Block Exemption. If the licence is exclusive, these restrictions can be circumvented by including a right to terminate the agreement if there is a challenge to validity of the licensed patents. In addition, non-challenge and termination clauses solely concerning know-how are not prohibited, as it allows weaker licensors to license stronger licensees without the fear of a challenge once such know-how has been absorbed by the licensee.[2]

## What other practical points can arise on termination?

Once the parties have agreed the scope of the termination rights, it's equally important to consider the consequences of that termination. For example, a licensor would want to ensure that all confidential information and/or materials are returned or destroyed, that all sublicences terminate and that the rights granted under the agreement automatically cease. This will be of particular concern if the licence has been terminated due to material breach.

While it may be difficult for a licensee to resist these sorts of provisions, there could be significant practical consequences if the licence terminates on short notice. If it has contractual obligations to supply licensed products to other third parties for onward sale, or if it is in the middle of manufacturing further products with another third party, then losing these rights could be very damaging to the business. There are also wider ethical considerations if the licensee is in the middle of clinical trials for a pharmaceutical drug product and such programs are unable to continue, or where termination would result in patients losing access to medicines.

A common solution to tackle some of these concerns will be to negotiate a transition period following termination, to allow the licensee to dispose of existing stocks of products for a set period of time. This may be mutually beneficial, as a licensor would still expect to receive royalties on any further sales during this period. There are also a number of licence provisions that would need to remain in force beyond termination, including confidentiality provisions, auditing rights, and liabilities.

# Part 6—Dispute Resolution and Enforcement

As with termination, while the parties will of course plan for a long and successful partnership and hope that the contractual dispute provisions are never required, it's important to plan for disagreements and the appropriate forum for resolving any such matters.

## Why would English law be a good choice for an international patent licence?

English law adopts a "freedom of contract" approach, meaning that contracts governed by English law are interpreted by reference to the objective meaning of the contract language. This allows for a certain level of predictability in the way a contract will ultimately be interpreted and enforced by the courts, which can allow disputes to be avoided or resolved without court proceedings, as the contract will be clear and self-standing in prescribing the parties' rights and obligations. The English common law system is also familiar to other nations around the world, including Canada, Hong Kong, Australia, and Singapore.

These principles can be particularly beneficial in the context of a complex patent licence agreement with an international element, as the parties will want certainty as to the enforceability of critical commercial terms that have been negotiated at length and agreed contractually.

## How do the parties decide on the appropriate dispute forum?

This will be influenced by the locations of the respective parties to a certain degree. If the licence agreement involves two UK-based companies, this may be a fairly straightforward discussion as both parties may be familiar and comfortable with using

the English court system. However, even where a licence involves multi-national parties, it is still common for parties to elect for the English courts. The UK judiciary are highly experienced in resolving international commercial disputes involving technical subject matter and the courts offer quick interim injunctions and a range of remedies for international cases.

Despite the potential advantages of court litigation, there are many reasons why arbitration is often more desirable for cross-border licence agreements. The confidentiality of the arbitration is a key reason for this, as the parties may wish to keep the details of the dispute out of the media and a licensor may also want to avoid bringing this to the attention of its other licensees. We summaries the key differences between the court and arbitration processes below:

## Should the parties consider a multi-tiered dispute procedure?

A multi-tiered dispute resolution clause (sometimes referred to as an "escalation" clause) typically requires senior officers of the parties to engage in good faith negotiations to try to resolve a dispute for a set period of time, followed by more formal mediation or other non-binding ADR process, followed by binding arbitration (or litigation) if no resolution can be reached.

A well-drafted multi-tiered clause can help to: (i) provide the opportunity to resolve disputes in a less adversarial setting; (ii) preserve ongoing commercial relationships; and (iii) save time and money. The risk of arbitration or court proceedings at the end of the process can serve as an incentive for parties to reach an amicable arrangement at an earlier stage.

However, parties may find that these provisions are too stringent and create a number of procedural obstacles when a claim needs to be pursued. They can sometimes favor a defendant, as various stages of prolonged negotiation may simply provide that party with further time to evade its contractual obligations or put a defensive litigation strategy in place. In addition, leaving aside contractual duties, any party bringing a claim should already be considering alternative means of resolving the dispute without recourse to litigation or arbitration. This is particularly the case where terminating the contractual relationship is not a desired path to take. For this reason, not including a complex multi-tiered dispute mechanism in the licence can give greater flexibility and avoid unnecessary delays.

## Commencing a dispute: procedure and strategy

In the unfortunate situation where there is a breakdown of relations between the parties or a fundamental disagreement over contractual obligations, more often than not there is a commercial solution without the need for adversarial proceedings. However, having a clear enforcement strategy at the outset of such dispute can help a party reach its desired objectives as swiftly as possible. The

| | Litigation in England and Wales | Arbitration |
|---|---|---|
| ***Flexibility*** | Court rules apply to process which must be followed. | Parties can decide the process, although in reality the parties follow a process which is similar to litigation with minor differences (such as a more streamlined disclosure) |
| ***Timing*** | Governed by the court timetable | Private sector, so potentially faster (subject to availability of good arbitrators) |
| ***Location*** | Usually London or one of the regional centres | For the parties to select, although the location is generally the "seat" of the arbitration, which means procedural rules of that state become relevant |
| ***Confidentiality*** | Potentially public | Generally private |
| ***Fees*** | Court fees relatively modest depending on the value of the claim | Tribunal members paid for by the hour, plus modest fees to the arbitral institution |
| ***Finality*** | Possibility to appeal (*i.e.*, UK Court of Appeal, Supreme Court) | Limited grounds for appeal |
| ***Enforcement*** | Subject to mutual recognition treaties, which can result in challenges when enforcing a judgment in foreign jurisdictions | An arbitral award is enforced and recognized through the New York Convention, which has around 168 signatories (including the UK). This means it is normally simpler to enforce an arbitral award than the judgment of a national court |

steps that a party can take to put itself in the best possible position include:

- Carefully checking the dispute provisions in the licence agreement before jumping into a formal dispute, to avoid committing inadvertent and unnecessary breaches. This will include following the contractual dispute procedure (such as commencing good faith negotiations with senior personnel) and ensuring any formal notice provisions are properly complied with.
- Acting quickly if there is any time sensitivity in the relief sought. In particular, if a party is seeking an interim injunction or other emergency relief, unless there is good justification, it cannot afford to spend weeks on end deliberating whether or not to commence proceedings.
- Considering whether there are any relevant exclusions or limitations on liability in the licence, which may impact the breach in question and the potential losses that may actually be recoverable from the other party.
- Gathering facts and evidence from the relevant people involved as early as possible, to ensure key documents are preserved and that factual information is collected while fresh in the mind of those involved.
- Seek external legal advice at this early stage and ensure advice given as part of this process is not spread too widely in the organization (to ensure it can benefit from privilege).
- If termination is a potential remedy, where appropriate, send a formal notice seeking a cure to the breach at an early stage and expressly reserve the right to terminate. This raises the stakes for the opposing party.
- Taking a step back and thinking about the ultimate end goal, how far the business is prepared to go to protect its position, and what a satisfactory outcome to the dispute might look like (even if this may not be the perfect result).

Of course, it is notoriously difficult to predict how licence disputes will unfold and much depends on how the other side reacts and engages with the process. If there is motivation and engagement on both sides, it is quite common to have: (i) an open line of legal correspondence asserting your strict legal rights and (ii) a "without prejudice" line of communication in parallel to this, to negotiate an acceptable settlement position.

## Conclusion

Any patent and know-how licence should strike a balance between protecting the licensor's valuable IP, while allowing the licensee the freedom it needs to successfully exploit and commercialize the licensed products (which ultimately benefits both parties). As illustrated above, there are many complex elements to these agreements and given the long-term nature of the contractual relationships it is important to give due consideration to the legal and commercial consequences of the deal.

A common mistake is to focus too heavily on short-term priorities of securing the licence deal, without planning for future needs and how the licence relationship may evolve as the respective businesses grow. For example, a start-up company taking out a licence may plan to outsource some of the development work to another partner and want to sell its business after a few years. Without securing appropriate sublicensing and assignment rights in the licence agreement, this could lead to much more difficult discussions further down the line and hinder the business plans. Hope for the best and plan for the worst: parties need to be realistic by ensuring appropriate termination and dispute resolution provisions are discussed and drafted.

Accordingly, taking the time at the outset of the licence negotiations to focus on the headline commercial points and the scope of the licensed rights required by the business will help to make the subsequent contract drafting negotiations a much smoother and more cost-efficient process for all parties.

1. Commission Regulation (EU) No 316/2014 of 21 March 2014 on the application of Article 101(3) of the Treaty on the Functioning of the European Union to categories of technology transfer agreements.

2. Guidelines on the application of Article 101 of the Treaty on the Functioning of the European Union to technology transfer agreements, paragraph 140.