

Managing insolvency risk in US pharmaceutical collaborations and development agreements

Victor A Vilaplana, of counsel
Foley & Lardner LLP

The costs of bringing new medicines to market are huge – frequently several hundred million dollars. The long and arduous path generally begins with a small biotech firm or academic institution developing a piece of intellectual property, most commonly a patent or patent application, which has:

- successfully completed toxicology animal studies;
- had submitted an investigational new drug report to the US Food and Drug Administration; and
- completed a Phase I clinical trial to evaluate the safety and pharmacological effects in human subjects of the particular drug, and a Phase II clinical trial to evaluate the effectiveness of the drug for a particular disease.

In order to bring the drug to market it must pass the Phase III clinical trial, which is the pivotal human clinical trial to establish the safety and efficacy of the proposed new drug. It is at this stage that the small biotech firm or academic institution reaches out to big pharmaceutical companies for financial and research and development support in the form of a collaboration and development agreement.

These collaboration and development agreements (CDAs) have certain common features relevant in the bankruptcy context. First, they contain a clause by which the small biotech firm grants a licence – generally on an exclusive basis – to the big pharma company with respect to the intellectual property being developed. The licence is frequently limited to a certain field, contains permission to sub-licence and sometimes sets out territorial limitations as well. CDAs generally contain cross-licensing provisions by which the big pharma licenses back to the small firm any intellectual property owned by the big pharma which is necessary for the small firm to carry out the research activities assigned to it under the CDA. Most commonly, the licensee will pay a one-off fee to the licensor upon signing the CDA, then staggered payments as the research programme progresses, and finally royalty payments once the intellectual property is generating an income stream.

In addition to the licence, the CDA also sets forth the term of the collaborative research programme which will implement the agreed research plan. The plan will allocate between the licensor and the licensee functions such as:

- the assignment of full-time employees;
- the exchange of information; and
- the creation of a joint research committee to determine overall strategy to make corrections to the research plan as necessary and to monitor and assess the progress of the research programme.

In addition, the CDA will allocate the responsibility for preparing and sharing records and reports reflecting the work done and the results achieved

through the research programme. In short, the CDA contains a variety of monetary and non-monetary obligations between the parties.

The licensing of intellectual property provides the mechanism by which the original inventor can retain sufficient ownership of the invention to share in the final economic reward, while sharing some of the reward with those who provide the financial and research and development support necessary to achieve economic success. Licensing also provides a mechanism by which an inventor who has identified more than one field in which his or her invention may have application can find partners for each field without risking the possibility that one partner's narrow focus will deny the inventor the rewards of development in other fields.

Although an outright sale of the intellectual property is an alternative to a licence, such a sale has certain consequences which make it less desirable, at least from the inventor's point of view, including the following:

- It results in the original creator losing his or her personal stake in the intellectual property;
- It is often difficult to establish the fair market value of an idea at an early stage; and
- Allowing the creator to retain an interest in the future financial rewards encourages innovation and competitiveness.

Therefore, protecting the licensee's interests in the event of the bankruptcy of a licensor is of paramount importance in all knowledge-based industries. If the licensee's interest can be extinguished in a bankruptcy by the licensor, big pharma companies will be reluctant to enter into CDAs and spend the significant amounts of money necessary to complete the product development process. This is especially true in the high-technology and biotech fields, where a licensed idea often originates in a small venture highly vulnerable to financial difficulty.

From the aspect of public policy, it is important to protect IP licensing from disruption by the insolvency of the licensor as:

- it provides a means to fund small high-technology companies. For example, the grant of a licence from Genentech to Eli Lilly for rights to recombinant human insulin made it possible for Genentech to fund research and testing for other therapies which Genentech marketed on its own behalf;
- it permits the full and speedy use of an innovative product for the benefit of all society.

Through licensing, the resources of the licensee are used to promote the worldwide use of a particular product – something generally beyond the means of the inventor; and

- licensing encourages innovation and creativity by allowing the small innovative creator to retain ownership of its creation.

CDAs as executory contracts under the US Bankruptcy Code

The bankruptcy risks associated with a CDA arise in the context of Section 365 of the Bankruptcy Code since CDAs will almost certainly be "executory contracts" under that section. Although the code contains no definition of an 'executory contract', and there are many court decisions interpreting that term, for purposes of this chapter it is sufficient to rely on the most widely accepted definition, the Countryman definition (after Harvard law professor Vern Countryman), which is that it is a contract with respect to which substantial performance is still due by both parties, such that failure to perform by one would excuse performance by the other.

As an executory contract, a CDA is capable of being assumed, assumed and assigned, rejected or ridden through the insolvency of either party. Of the four alternatives available regarding a CDA (assumption, assumption and assignment, rejection or ride-through), it is assumption and rejection which have raised the most significant concerns for licensors and licensees.

Assumption by debtor licensee

With respect to assumption, the courts have been divided as to whether to adopt an actual or hypothetical test under Section 365(c). Section 365(c) provides that a trustee or debtor-in-possession "may not assume or assign any executory contract... if: (1)(A) applicable law excuses a party, other than the debtor, to such contract... from accepting performance from or rendering performance to an entity other than the debtor or debtor-in-possession, whether or not such contract... prohibits or restricts assignment of rights...; and (B) such party does not consent to such assumption or assignment".

The courts that have adopted the hypothetical test rule rely on the "plain meaning" of the statute. Those courts hold that by its terms the statute prohibits a debtor from assuming an executory contract in the absence of the other party's consent,

where applicable law precludes assignment even though the debtor does not intend to make such an assignment.

The actual test states that where the debtor or debtor in possession does not intend to make an assignment of the executory contract, the assignability of the executory contract is irrelevant to the decision of whether it can be assumed.

Thus, in US jurisdictions which follow the hypothetical test, whether a CDA can be assumed by the debtor licensee in a Chapter 11 turns on whether such licence is assignable under applicable non-bankruptcy law. Since intellectual property may take various forms (eg, copyrights, patents or trademarks) and since each form of intellectual property has its own distinct legal regime, it is necessary to examine each legal regime to determine whether the intellectual property in question is assignable under non-bankruptcy law.

In the case of patents – the most common form of intellectual property involved in CDAs – non-exclusive licences are generally considered personal to the licensee and therefore cannot be assigned without the licensor's consent. Allowing free assignability of a non-exclusive patent licence would jeopardise the ability of the licensor to control the identity of its licensees and would place the licensee in a position to compete with the licensor in marketing licences for the patent. It has not, however, been settled whether the hypothetical test will be applied to exclusive licences, although some decisions do apply the test to such exclusive licences.

The result of the hypothetical test is that if a licensee files a Chapter 11 and seeks to assume the licence, it will not be allowed to without the licensor's consent. The hypothetical test applies in important bankruptcy jurisdictions such as California and Delaware, but not in New York.

An illustration of the application of the hypothetical test is the *Catapult Entertainment* decision. *Catapult Entertainment*, a Chapter 11 debtor, filed a motion to assume certain non-exclusive patent licence agreements under which it was the licensee. *Catapult* intended not to assign the licences, but rather to continue to operate under and honour the terms of the licence. The licensor would not consent to the assumption. The bankruptcy court allowed the assumption but the appeal court reversed that decision, holding that since such a licence was not assignable under applicable non-bankruptcy law, it was also not assumable.

In representing licensees in those jurisdictions which have adopted the hypothetical test, consideration must be given to how to protect the

licensee in the event that it files for bankruptcy but would want to preserve the possibility that to continue to use and honour the licence agreement. One alternative is for the licence to provide that in the event of a bankruptcy of the licensee, the licensor consents to the assumption of the licence, but not to the actual assignment to any third party.

If the licence cannot be or is not assumed, an alternative under the Bankruptcy Code is that it 'ride through' the bankruptcy. If the licence rides through because it is neither assumed nor rejected, the debtor retains the benefits as well as the burdens of the contract and all claims that arise from the breach of such contract are not discharged or otherwise affected by the Chapter 11 reorganisation plan.

Rejection by debtor licensor

While concerns regarding assumability generally arise when the debtor is the licensee (as in *Catapult Entertainment*), the other significant bankruptcy issue involving CDAs arises where the debtor is the licensor and seeks to reject the licence.

Under the Bankruptcy Code as originally enacted, certain courts held that a licensor in a Chapter 11 could reject the licence and sell the intellectual property, free of any claim by the licensee, to another party. In effect, a party could sell the same intellectual property twice: once before bankruptcy through a licence and a second time after bankruptcy by rejecting the licence.

As a result of a storm of protests by the technology licensing community in the United States, Congress passed an amendment to the Bankruptcy Code, which in effect overruled those decisions. The amendment is found in Section 365(n) of the Bankruptcy Code and is designed to protect the right of licensees to retain the use of intellectual property conveyed prior to the licensor's bankruptcy.

The Bankruptcy Code now treats IP licences in a manner parallel to the treatment of real estate leases under the Bankruptcy Code. This is appropriate because in both real estate leases and IP licences, the underlying property is unique. When the lessee or the licensee is threatened with loss of the use of the property, it is not possible to obtain precise cover.

Section 101(35A) of the Bankruptcy Code broadly defines 'intellectual property' to mean trade secrets, inventions, designs, patents, patent applications and other specified types of such property.

Under Section 365(n), in the event that an

executory contract under which the debtor is a licensor of IP rights is rejected in the licensor's bankruptcy, the licensee may choose one of two options:

- The licensee may treat the rejection as termination of the licence, leaving the licensee with a pre-petition claim for breach of the licence; or
- The licensee may elect to retain its rights under the licence as such rights existed immediately before the bankruptcy case was begun. The law recognises that continued affirmative performance of an IP licence by the bankrupt licensor may be impractical (eg, a bankrupt licensor will generally be unable to perform covenants calling for continued research to develop the licensed intellectual property), but it protects the licensee's rights to the intellectual property as they existed at the time the bankruptcy case was commenced.

Thus, if the CDA granted exclusive use to the licensee, such exclusivity would be preserved to the licensee. The licensee has the right to compel specific performance (ie, to enjoin the licensor from licensing to another the rights granted in the CDA). However, if the licensor has chosen to reject the CDA, the licensee, although entitled to retain its rights, cannot otherwise compel the performance of post-petition obligations. For example, the licensee could not compel the licensor to defend the licensor's patent against an infringement claim.

CDAs are not generally standardised. Rather, each CDA is the product of the specific negotiations and interests of the licensor, the licensee and other interested parties. It is not unusual for the licence to be one of several agreements governing the working relationships between the licensor and the licensee. The licensor may have contracted to supply the licensee with a product incorporating the intellectual property or may have agreed that the licensee would have access only to information necessary to produce the licensed intellectual property in the event of the licensor's inability or unwillingness to supply the licensee. The use of a third-party escrow is a common method of implementing such an agreement.

As a counterweight to the rights granted to the licensee to elect to retain the licensed rights, the licensee is obligated to make all royalty payments

and is further required to waive any right to the set-off of damages that it may have incurred as a result of the debtor's rejection of future performance obligations. However, the licensee does retain a general unsecured claim for damages from rejection as a breach of contract. This is in contrast to the treatment of real estate lessees under the Bankruptcy Code. Under Section 365(h)(2) a lessee of real property that remains in possession may offset against the rent any damages caused by the debtor's non-performance of any obligations under the lease, but otherwise has no damage claim.

CDAs frequently require that the licensee not only make royalty payments, but also provide various forms of non-monetary consideration. The Bankruptcy Code does not deal with what happens to the non-monetary obligations due from the licensee. According to the legislative history of the Bankruptcy Code, most such obligations will survive and the licensee will be required to perform them in addition to making the royalty payments. However, there may be some obligations of which the licensee may be relieved by a court on the grounds that they are so closely tied to reciprocal duties of which the licensor was relieved by rejection that it would be inequitable to make the licensee perform them (although this does not apply to royalty payments, which are mandated by the statute). This issue must be left to the equitable discretion of the bankruptcy court in the light of the circumstances of each case.

Conclusion

The law of executory contracts in bankruptcy in the United States is complex and surprisingly non-uniform. Thus, in counselling parties entering into CDAs it is important to understand which laws may apply (eg, has the jurisdiction adopted the hypothetical test?) and how courts in the relevant jurisdiction have used their equitable powers to balance the rights and duties of the licensor and licensee. For many non-US attorneys it may come as a surprise that the United States, with a national bankruptcy statute enacted under a constitutional directive to create a uniform law, has such variation and unpredictability. However, the highly individualised and customised nature of CDAs necessitates such individualised judicial examination and customised relief.