# Cross-border transactions: A roadmap for commercial arrangements between North American and European companies

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## Abstract

Major advances and breakthroughs in the biotechnology industry are increasingly reached through cross-Atlantic strategic alliances and collaborations. This paper explores some of the distinctions between biotech transactions that are between parties in different countries, particularly the US and EU members.

## INTRODUCTION

When analysing or structuring cross-border partnerships, it may be important to consider the complexities, conflicts or subtleties of local laws. At the same time, there are cardinal rules that apply in all situations regardless of where the parties are domiciled.

The focus here is strategic agreements – often referred to as CRADAs (Cooperative Research and Cooperative Agreements[1]). These are generally tripartite agreements – research, development and commercialisation. In more cases than not, parties never get to the commercialisation phase because of the difficulties encountered in the clinical development stage in terms of proving efficacy and funding the clinical process.[2]

## DOCUMENTING THE TRANSACTION – THE BASICS

As a general proposition, there are a number of rules that apply wherever the parties are located.

### General rules regardless of the location of the parties

Parties must agree upon clearly defined *end-points* for the research phase; they must clarify what each brings to the table in terms of intellectual property, including know-how, trade secrets and technical information. If this is not clear at the outset, parties may find themselves in a dispute as to the ownership of intellectual property that results from the research.

Perhaps the most important issue after the foregoing is carefully defining *termination rights*. More often than not, there comes a point when these agreements terminate; there should be a mechanism to determine how the valuable data that have been generated and/or intellectual property and/or drug substances or other materials will be divided among parties. This is often the case when the agreement is terminated not because the research has failed; but rather, for one reason or another, because one party no longer wishes to continue with the project as a result of management changes, investors requiring a company to narrow its focus or reduce its number of projects, or personnel changes – particularly in the case of a principal investigator or important steering team member.

Other examples of events that can trigger the termination of the agreement include the end of the term; the

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bankruptcy of one of the parties; a breach or other default; failure to reach milestones; a mutual agreement to that effect, an initial public offering (IPO) or third party offer for business, or a deadlock. Also, the terms of the contract may cease to be in effect, but the parties may want to continue their relationship at a different level, for example to pursue further research or continue manufacturing certain products.

**Dispute resolution mechanisms ensure expeditious adjudication of contentions between the parties**

In the same regard, it should be evident that parties must provide for *dispute resolution mechanisms* that can be used during the course of the agreement when there are disagreements that cannot be resolved on an informal basis. The goal should be to provide for procedures which result in speedy decisions. We suggest a streamlined form of arbitration. There is a trend in biotech transactions to employ what is known as 'baseball arbitration',[3] a procedure often used in the past to adjudicate disputes over a certain monetary amount. Essentially, this calls for each party to simultaneously submit a written statement of their positions and proposed resolution, including all relevant supporting information – scientific, technical, etc. The arbitrator must make a determination by selecting the resolution proposed by one of the parties that, as a whole, is the most fair and reasonable, taking into account the totality of circumstances. The parties can also allow for the arbitrator to meet with the parties, either alone or together, if he deems it necessary to make a determination.

**Recourse to arbitration can offer many advantages: informality, ease of enforcement, speed and confidentiality, to name a few**

Parties should carefully draft the arbitration clause. Under the doctrine of severability, the validity of an arbitration clause is separate from the contract in which it is found. The clause should detail the type of disputes to be adjudicated, the number of arbitrators to be used and their method of selection, the particular jurisdiction and venue in which the disputes are to be adjudicated, and the language(s) used in written and oral proceedings, as well as the need for translation if necessary. Arbitration clauses are rarely invalidated, unless a party can show fraud, duress or a contravention of public policy.

Arbitrators are usually experts in the subject matter of the dispute. They are selected by the parties and empowered by agreement to render a final decision, which the parties can agree will be binding upon them. The grounds for vacating an arbitration are extremely limited (eg corruption, fraud, misconduct, arbitrator's bias or excessive use of its powers). The arbitrator has broad power to adjudicate the dispute, including the ability to render a decision in equity.

The arbitration process is overall less formal than that of a court-litigated dispute. Other recognised advantages include ease of enforcement, speed, confidentiality, choice of decision maker and reduced costs. That being said, arbitration is not always cheap, nor fast if the agreement does not contain safeguards to avoid undue delay of the proceedings by one party.

Confidentiality is largely dependent on the attitude of the parties and witnesses, and while the parties may not want their dispute to become public knowledge, the results may have to be disclosed for enforcement or financial reporting purposes. Moreover, decisions are not subject to appeal and the neutrality of the arbitrator must be carefully reviewed through disclosure statements of conflicts of interests.

## Special rules for international transactions

While most biotech agreements in Europe, Asia and North America are written in English[4] and generally follow an Anglo-American form, the *applicable law* is often times that of a country where the law is based, or the Roman system in which most issues are codified. In the case of European parties, whether it be the law of England and Wales, or a continental European country, the EU Directives and Regulations are also applicable. In fact, in large transactions that meet particular thresholds, it is possible that even an agreement between two US companies or

**Given the subtleties and peculiarities associated with each legal tradition, it is sometimes necessary to have local counsel 'vet' the agreement**

two European companies that will affect the marketplace in Europe and/or America must still not run afoul of the antitrust laws in the USA[5] and the Competition rules in Europe.[6] In that regard, the US Court of Appeals for the DC Circuit recently recognised the right of foreign purchasers of vitamins and vitamin products to recover treble damages under US antitrust laws from manufacturers and distributors that participated in a global conspiracy to fix prices of vitamins sold both within *and* outside the USA, so long as the conspiracy's 'direct, substantial, and reasonably foreseeable effect on domestic commerce' gave rise to a claim under the antitrust laws.[7] That ruling was ultimately set aside by the justices of the US Supreme Court who unanimously decided that such damage claims could not be automatically brought by foreign drug manufacturers.[8]

**Tax considerations, in addition to antitrust and/or competition regulations, are important factors to take into account in international transactions**

Other practical issues to consider in the international transaction are the importance of *tax treaties*. In many countries, royalty income is taxed at a lower rate than ordinary income and the withholding rules on royalties paid between two countries vary depending upon the countries. For example, in one transaction the authors are familiar with, royalties paid from an Italian company to a Luxembourg entity would be subject to a 35 per cent withholding in Italy; however, interposing a Dutch patent exploitation company in the middle would result in a 5 per cent withholding between Italy and the Netherlands, and no withholding to Luxembourg. In the case of a Luxembourg 1929 Holding Company (a statutory creature that does not engage in operations of a business directly and can only have its income from royalties, dividends and the like), there is no tax for such income. Similarly, it is possible in some European countries to negotiate the tax ramifications with the tax authorities beforehand, particularly if the country is trying to encourage the growth of technology and research and development within its borders.

It is not uncommon for the governing law to be that of a third country. In such circumstances, parties should obtain *local counsel review* or 'vet' of the agreement to ensure that there are no local nuances or other legal issues that need to be considered. As a general rule, in the Civil Code countries, there is usually something in there for everybody, and for English-speaking parties, it is well to invest in an English translation of the Code. The results are generally the same under any system, but the process of getting to the end-point is different. In the authors' experience, when working with another legal system, one can generally start out by discussing how a certain result would be obtained in the system that he or she is familiar with, and then ask local counsel how the same result would be obtained under the other system.

A couple of examples of important nuances between Code and Common Law systems are as follows:

- Common Law has the *Parole Evidence Rule*, ie in the absence of a latent ambiguity, a fact-finder cannot go outside the four corners of the document to ascertain the parties' intent. In Code countries, a fact-finder generally tries to ascertain what the parties intended and specifically goes outside the agreement to try to fashion a remedy consistent with what the fact-finder believes was the intent.[9] Accordingly, the 'Whereas' clauses setting forth what each party desires and expects as a result of having entered into the agreement become very important if there is a dispute and the fact-finder is trying to determine what was intended. As a general rule, in Common Law countries, the 'Whereas' clauses are not considered to be part of the agreement, and therefore the parties attempt to provide for every possible permutation that may result from the intended collaboration in the agreement. The Code draftsperson is more inclined to set forth the broad parameters respecting the outcome the

parties intended to obtain as a result of the contemplated agreement. They agree to agree.[10]

**In New York, 'best efforts' requires doing everything that is necessary to achieve a desired result . . .**

- In New York, the concept of '*best efforts*' has its roots in a case where the seller of a brewery was to receive a part of the consideration for the sale out of the future revenue that the business would generate. The purchaser was required to use 'best efforts' in operating the business to bring about maximum revenues. When it was shown that the purchaser reduced the advertising budget from what it was when the seller was operating the business, the Court held that the purchaser had not applied 'best efforts'.[11] Generally, a party is not supposed to bankrupt itself in applying 'best efforts', but it must do everything that it could do or, normatively speaking, do everything that ought to be done to achieve the desired result. In Switzerland for example, the use of the term 'best efforts' is seen as qualifying the obligation. In other words, before the obligation is qualified, the party is required to do something. If the obligation is qualified by the term 'best efforts', the requirement to perform the obligation becomes something less than full performance. Under the Italian Code, a debtor is expected to perform his obligations with the '*diligence of a good pater familias*' (ie a good father) as a general '*regulae iuris*'; duties to behave according to the rules of fairness and in good faith equally apply to both parties in the transaction.[12]

**. . . In Switzerland, an obligation qualified as such becomes something less than full performance**

## CARVING UP THE PIE – THE SPECIFIC ALLOCATION OF RISKS AND BENEFITS

### Intellectual property and proprietary rights

**A number of international intellectual property treaties may affect the terms negotiated by the parties**

Each party's intellectual property (IP) rights prior to entering into an agreement should be explicitly clarified by very tight definitions. In some cases, it is wise to annex to the agreement lists prepared by each party of inventions, know-how, patent rights, technical assistance, interest in joint developments and interest in third-party developments, as well as any other rights that are necessary to the project that a party has at the outset. The products arising out of the research programme similarly must be carefully delineated.

**Intellectual property rights of each party should be clearly defined prior to entering into an agreement**

Joint ownership of a patent is handled differently in different countries. In the USA, without an agreement, joint ownership of a patent is akin to joint ownership of a bank account: either party can exploit all of the rights by granting an exclusive licence subject only to the rights of the other owner.[13] It also hampers the ability of one owner to sue for infringement, secure the patent and/or exclusively license.[14] In Canada, a joint owner does not have a right to license to a third party without the consent of the joint owner, but each joint owner can somehow exploit the patent for themselves.[15] In the UK, joint owners can do nothing unless and until there is an agreement between them.[16]

In entering international agreements, there must be an appreciation of the fact that IP is truly an international area of the law. Hence, it can be affected by a number of international treaties.

The *Agreement on Trade-Related Aspects of Intellectual Property Rights* (TRIPS),[17] for instance, has two major goals: (i) making IP protection a central part of US foreign trade policy and (ii) improving. international IP protection. Prior to TRIPS, many countries had limited or non-existent laws protecting IP rights, and other countries' laws were not necessarily respected in another country.[18] TRIPS addresses differences between developing and developed countries by giving developing countries a 10-year period to become TRIPS-compliant. Moreover, it ensures developing countries' access to technologies that are imperative to

development. Patent protection for inventions must be available for a minimum term of 20 years starting from the filing date.[19] However, despite unprecedented level of positive rule-making, the IP provisions of TRIPS leave substantial room for countries to exercise regulatory control over pharmaceutical pricing.

**The Patent Cooperation Treaty allows an IP owner to designate each country in which there is potential filing interest at the time an application is filed**

The decision on where to file patents needs to be understood. The *Patent Cooperation Treaty* (PCT), a multilateral patent treaty, allows an IP owner to designate each country in which there is potential filing interest at the time an application is filed. The IP owner can also designate one or more of a list of patent organisations covering a number of countries, such as the European Patent Office for EC countries or the Eurasian Patent covering Russia and a number of Soviet republics. If a patent is filed in the USA, a foreign counterpart application may be filed for up to one year after the filing date in any of the countries that are members of the *Paris Convention for the Protection of Industrial Property (1883)*, a treaty of mutual recognition between parties as to patent application filing dates. A foreign counterpart application obtains the benefit of a US priority date, as opposed to the date of filing in the foreign country.

**Database rights in Europe confer a 15-year term of protection to the corporate maker of a database**

The benefit of the PCT is that it allows filing delays in these other countries for up to 30 months from the US filing date; however, a party must still file a national application in each country in which protection is desired. The advantages are the delay of national filing costs, the conduct of novelty searches and examinations at an international level, and the ability to keep one's option open in many countries for a relatively low cost. If the intent is to license out the patent on a country-by-country basis, the potential licensee may ultimately pay the costs of prosecution in countries in which the licensee is interested.

Under the *European Patent Convention* (EPC), a single European procedure for the granting of a patent is provided for. Infringement issues, however, are dealt with by national law. There are distinct differences relating to patenting the human DNA sequence in the USA and Europe. Under US Patent and Trademark Office (USPTO) Guidelines issued in January 2001, single nucleotide polymorphisms (SNPs), genes and protein structures of unknown function lack utility and are therefore not patentable. Europe strengthened its utility standard with respect to biotechnology patents, requiring that an invention is only susceptible of industrial application (a requirement for obtaining a patent in Europe) if it can be made or used in any kind of industry, including agriculture.

Under Article 53(a) of the EPC Treaty, inventions, the publication or exploitation of which would be contrary to '*ordre public*' or morality, are not patentable, provided however that exploitation is not deemed to be so contrary merely because it is prohibited by law or regulations in some or all of the contracting states. In general, the public and many officials are against patenting human DNA sequences, arguing that doing so is unethical.

Database rights are increasingly becoming important in protecting a party's investment in obtaining data. Such a right may become useful as a result of advances in bioinformatics, the development of gene databases, and compound databases among others. A database right, as opposed to an agreement conferring rights to a database, is a European right providing a 15-year term of protection, and it is available only to a corporate maker of a database.[20] To qualify, the corporation must be formed under the laws of a European Economic Area (EEA) state, and either have its principal place of business within the EEA or its registered office within the EEA and ongoing operations within EEA states. A partnership, on the other hand, must not only be formed under the laws of an EEA state, but it must have its principal place of business there as well.

## Contributions and incentives

Once the parties have clearly determined what they are negotiating for and what they are each bringing to the table, the next thing is to determine who does what and who pays for what. Contributions can consist of up-front payments of R&D costs, resources and technology, or investments in the forms of loans, convertible debt, or equity. The degree of collaboration should also be assessed, ie whether there will be joint research or funding of development, manufacturing, commercialisation and marketing. Also, the agreement should provide for the possibility of opting in and out at different stages in time.

**Successful collaborations must be supported by some kind of financial incentives, such as royalties**

Successful collaborations must be supported by some kind of financial incentives to reward each party's assumption of risks and costs. If the payment of royalties is envisioned by the parties, the following matters should be determined and addressed in the agreement: (i) currency, date and manner of payment; (ii) definition of net sales; (iii) term and renewal; and (iv) tax-related issues if the royalty income passes from one state to another. Other forms of monetary relief include milestone payments, forgivable loans or equity financing.

Recent examples of US–EU transactions include the conclusion of an agreement between Tibotec Pharmaceuticals Ltd, a subsidiary of the US-based company Johnson & Johnson, and the International Partnership for Microbicides (IPM) in London,[21] and that between Amphora Discovery Corp. – based in North Carolina – and the French corporation Aventis SA.[22]

## Management of joint activities

**Activities undertaken jointly can be overseen by project teams or steering committees**

The establishment of partnerships requires a cooperative oversight of the activities that are undertaken jointly. To ensure a smooth running of operations, there must be a common understanding of the role and responsibilities of each parties, as well as adequate means for assessing and reviewing performances. The establishment of project teams or steering committees is one way to do that. Managing personnel should be selected from each side according to the parties' wishes to monitor compliance with the terms of the agreement within set budgetary allocations and to carry out the agreement. Often different personnel are appropriate to a particular phase of the agreement, eg scientists for research; clinical trial specialists for development in order to obtain statistically relevant data, and business development personnel for the commercialisation stage.

## CONCLUSION

We end where we began. It is important for the parties to think through the scope and the extent of the relationship they want to enter into with their foreign counterpart; review the nuances of different legal systems; and review the treaties applicable when different legal systems interact with one another. Combining expertise, human and material resources, as well as know-how will ultimately help to bring innovative products to the market faster, and parties will have a clearly defined agreement as to their respective rights and obligations.

### *References and notes*


1. CRADAs as a term came into prominence in the mid-1980s after the passage of the Federal Technology Transfer Act (FTTA), 15 USC §§1501–1534, which for the first time set forth procedures and allowed US government agencies to enter into research and development agreements with the private sector; if the results merited it, the government agency could directly enter into exclusive and/or non-exclusive licences and even give a commercial party the right to exclusively prosecute and enforce patent applications and patents owned by the US government. *See* Sidebottom, D. M. (2002), 'Updating the Bayh–Dole Act: Keeping the Federal government on the cutting edge', *Pub. Cont. L.J.*, Vol. 30, pp. 225–241.
2. While not always the case, the estimates of the costs of bringing a new drug to market range as high as US$802m, and it generally takes anywhere between ten and 15 years, or more in some cases. See DiMasi, J. A., Hansen, R. W. and Grabowski, H. G. (2003), 'The price of innovation: New estimates of drug

development costs', *J. Health Econ.*, Vol. 22, pp. 151–185. In this regard, it should be noted that originally the FTTA was applicable only to small companies but its applicability was extended to large companies by an Executive Order of President Reagan in 1987. *See* Exec. Order No. 12,591, 52 Fed. Reg. 13,414 (22nd April, 1987).

3. In Major League Baseball, when there is a contract dispute, the parties generally each give an independent arbitrator a specific dollar amount and the arbitrator is bound to choose one or the other, but is not permitted to 'split the baby in half'. The idea is that it brings people to a reasonable position, because if they suggest an amount that is unreasonable, the arbitrator will pick the other number.

4. If the agreement is written in more than one language, there should be an explicit provision to the effect that each version is equally recognised and binding.

5. The Sherman Act in the US prohibits any 'contract, combination in form of trust or otherwise, or conspiracy in restraint of trade or commerce' with other states or foreign nations; it also prohibits every monopolisation or attempts to monopolise any part of trade or commerce with other states or foreign nations. See 15 USC §§1 *et seq*. The Federal Trade Commission (FTC) and the Department of Justice (DOJ) Antitrust Division must receive pre-notifications of transactions involving the acquisition, disposition or transfer of assets or voting securities – including an acquisition of voting securities of a joint venture in formation – under the Hart–Scott–Rodino Antitrust Improvements Act of 1976. See 15 USC §§18a *et seq*. Additionally, the FTC and DOJ jointly issued a set of guidelines that equally apply to domestic and international intellectual property licensing agreements. See Antitrust Guidelines for the Licensing of Intellectual Property (April 1995), and Antitrust Guidelines for Collaborations Among Competitors (April 2000).

6. Under EU law, Article 81 of the EC Treaty (ex Article 85) specifically prohibits agreements that restrict competition within the common market (eg price fixing, geographical market sharing practices); they are deemed automatically void. However, the European Commission may provide certain exemptions if the agreements contribute to improving the production or distribution of goods or to promoting technical or economic progress. Important reforms recently came into effect, along with the enlargement of the EU to 25 member states. The New EC Merger Regulation 139/2004 – replacing Regulation 4064/89 – includes measures designed to better focus enforcement activities of EU competition law and reform the European Merger Control Regime procedures. See Commission Regulation (EC) No. 802/2004 of 7th April, 2004, implementing Council Regulation (EC) No. 139/2004 on the control of concentrations between undertakings. The notification requirements for proposed mergers are eliminated and replaced by a self-assessment by companies of their compliance with EU competition law. Enforcement of policies are more decentralised, and demand close cooperation between the European Commission, and National Competition Agencies (NCAs) and courts in member states. With regard to intellectual property agreements, new technology transfer block exemption regulations allow companies with little market share to act within 'safe harbours' and not have their licensing agreements for patents, know-how or software copyright scrutinised by EU competition law. See Commission Regulation (EC) No. 772/2004 of 27th April, 2004, on the Application of Article 81(3) of the Treaty to categories of technology transfer agreement.

7. *Empagran S.A. v F. Hoffman-LaRoche, Ltd.*, 315 F.3d 338 (D.C. Cir. 2003).

8. *Hoffman v Empagran*, 124 S.Ct. 2359.

9. The purpose of the agreement need not necessarily be expressed in the contract. For instance, under Quebec law, a contract's existence must be justified by a valid cause – ie a reason that determined each party to contract in the first place – that is not be prohibited by law or contrary to public order. *See Civil Code of Québec*, S.Q., 1991, c.64, §§1371, 1410 and 1411. Likewise under Italian law, the agreement must have a lawful '*causa*' which is not contrary to mandatory rules, public policy or morals. See Italian Civil Code, Art. 1325 and 1343. *Causa* is one of the most important and ambiguous term in the Italian juridical tradition; it has many philosophical implications. However, all interpretive theories refer to *causa* as the legal justification for the obligation.

10. There is a tendency in commercial matters for parties in all of these countries to come closer to each other's legal system as a result of globalisation.

11. *Bloor v Falstaff Brewing Corporation*, 601 F.2d 609 (2nd Cir. 1979).

12. See Italian Civil Code, Art. 1175 and 1176.

13. See 35 USC §262. Title 35, Section 262 of the United States Code provides that 'In the absence of any agreement to the contrary, each of the joint owners of a patent may make, use, offer to sell, or sell the patented invention within the United States, or import the patented invention into the United States, without the consent of and without accounting to the other owners.'

14. See *Schering Corp. v Roussel-UCLAF SA*, 104 F.3d 341, 345 (Fed. Cir. 1997).

15. See Canadian Patent Act, RSC, 1985, c. P-4, s. 42; RS, 1985, c. 33 (3rd Supp.), s. 16.

16. See Patents Act 1977, s. 36.
17. TRIPS was negotiated under the aegis of the World Trade Organization (WTO), along with other agreements, during the 1986–94 Uruguay Round negotiations. The WTO oversees the agreement and the resolution of disputes – including settlement procedures – on intellectual property issues between member states.
18. India did not grant patents for pharmaceutical products, nor did Brazil for pharmaceutical products or processes.
19. The USA revised its patent term to conform to a single Trade-Related Aspects of Intellectual Property Rights Agreement (TRIPS) standard, when it implemented the Agreement.
20. See Directive 96/9/EC of the European Parliament and of the Council of 11th March on the Legal Protection of Databases.
21. Tibotec provides a royalty-fee licence to develop, manufacture and distribute TMC120 as an HIV microbicide in resource-poor countries, while IPM bears responsibility for the development of the compound.
22. Aventis agrees to pay Amphora research funding, milestones and royalties on future product, in exchange for Amphora performing drug discovery at Aventis global research sites to identify small-molecule kinase inhibitors for multiple potential therapeutic targets.