Chapter 7
Private Contract Law

I. Introduction

Ultimately, genetic resources and associated traditional knowledge (TK) are transferred for R&D and other purposes from provider to users through private contracts which are legally binding documents between the two parties. Such contracts can take a number of forms, including bioprospecting agreements, material transfer agreements (MTAs) and collaborative research agreements.[296] These contracts may be considered benefit sharing agreements under the Nagoya Protocol provided they contain the terms for the sharing of benefits that may arise from the access and removal of the genetic resource and its utilization. The keepers of those genetic resources in the provider countries, whether they are the national ABS authority or an indigenous group, must therefore negotiate the terms of such contracts carefully in order to safeguard their interests.

Recent trends in ABS agreements show that "natural product discovery is found largely in smaller discovery companies, semi-governmental or governmental entities and universities around the world. Elements of large pharmaceutical natural products programs have been spun off into non-profits or semi-governmental entities, and compound libraries have been given away or sold off cheaply."[297] The International Federation of Pharmaceutical Manufacturers Association (hereafter IFPMA) estimates that of 19 pharmaceutical multinationals that previously had natural products programs, only 7 currently have such programs, most of them Japanese.[298] Laird and Wynberg point out that there is greater use of genetic resources and TK by the cosmetic industries, while ABS principles are not always understood in other industries such as botanicals and food/beverages.[299]

Negotiating contracts using knowledge of the law takes time and practice. Moreover, developing country negotiators often face informational and other disadvantages when entering into contract negotiations. A major factor limiting the ability of parties to freely agree to the terms and conditions in an MTA, which is the focus of this chapter, is that these contracts must respect applicable provisions in the respective IP and ABS laws, among other relevant legislation. It is for this reason that the bulk of this handbook is spent discussing these policies and regulations. While good negotiation will not overcome all inherent handicaps in negotiations, knowledge of policies, laws and some foresight will enable negotiators to come up with fairer MTAs that respect international and national ABS rules, and hopefully ensure outcomes that more adequately preserve and support provider interests.

This chapter is therefore written, like the other chapters, from the provider country perspective, and is designed to deepen understanding of issues which the provider country negotiator will want to bear in mind when negotiating such contracts. The chapter provides a concise guide to key points that developing country providers will want to bear in mind when negotiating an MTA, focusing on provisions that have a particular relationship to IP-related ABS issues. IP represents an issue that

[296] Some of the salient differences between various contracts are discussed in section II of this Chapter.
[297] Laird and Wynberg (2012), p. 7.
[298] Presentation of Mr. Andrew Jenner, Director of Innovation, Intellectual Property and Trade at UNCTAD's Ad Hoc Expert Group Meeting on the Development Dimensions of Intellectual Property: Biological Diversity and Access and Benefit Sharing, 16 April 2013. On file with the authors.
[299] Laird and Wynberg (2012), p. 7.

potentially cuts across a number of the terms and conditions contained in an MTA. The references to PIC and MAT requirements herein are therefore discussed in this context.

Key Points

⇒ A variety of contracts could come up in the course of ABS procedures including bioprospecting agreements, material transfer agreements (MTAs), joint research agreements, among others. They are benefit sharing agreements only to the extent that their terms contain a potential or actual benefit to the provider.

⇒ Genetic resources are often transferred from provider to user through private contracts called Material Transfer Agreement (MTAs).

⇒ Providers in developing countries may be at a disadvantage when negotiating contracts, and will want to know how to negotiate MTAs to safeguard their interests.

II. MTAs and other Private Contracts

A brief digression on terminology will help to focus the discussion of this chapter. First, an MTA needs to be distinguished from a general license. An MTA is the contract that underlies the physical transfer of a genetic resource from the provider to a user. It will be used to specify terms and conditions when, for example, a plant is provided to a botanical garden in a user country or when a monkey specimen is provided to a primate research center. An MTA will also be used when an actual virus sample is provided from a provider to a user, as in the case of the WHO SMTAs in Annex II.

The MTA will embody the conditions attached to that physical transfer, including what the user will be able to do with the genetic resource obtained, including, for example:

- what R&D the user will be able to undertake using the genetic resource;
- the extent to which replication, alteration or breeding of the genetic resource is permitted;
- how the benefits would be shared from any commercialization of the fruits of R&D on the biological resource being transferred;
- limitations on third party transfer, if any; and
- prohibition or permission to commercialize the transferred resource and associated TK, including the results of R&D.

The contract will also specify what ought to happen in the event that a party fails to honor the terms of the contract.

By contrast, a *license* is, under contract law, broadly speaking a legal agreement that embodies permission.[300] For example, a driver's license grants permission to drive, and a fishing license grants the licensee permission to fish in a given geographical area. These licenses basically grant

[300] Black's Law Dictionary, ed. 1999.

certain privileges by the government to the licensee. In the context of IP, a license refers to the permission to make or utilize certain intangible property that is owned by a licensor.[301] Such contracts set out the terms and conditions for the license, including how the licensee can utilize the intangible property, in what jurisdiction, for how long, and for how much (i.e., royalties). Patents, trademarks and know-how, in addition to other forms of IP, can all be licensed, and sometimes, depending upon the terms of the license, sub-licensed.

Underlying the notion behind an MTA and a license is that under both types of contracts the owner of the subject matter does not change. Licensors remain the owners of the intangible property in a license; the CBD makes clear that States have sovereign rights over their own biological resources. The underlying contracts simply set out the terms and conditions that bind the use of the underlying subject matter. Notwithstanding the use of the possible confusion created by the use of the term "deed", which is used to describe the model MTAs used by Australia, neither the MTA nor the license contract is considered a *sales* contract, which calls for a change in ownership and allows the new owner to freely dispose of the subject matter once title has passed. In this regard, MTAs may also be understood as a variation on a loan contract, where a physical object (the genetic resource) is leased without any change in ownership.

The distinguishing feature of the MTA, as compared to an IP license is that the subject matter involves a physical transfer (i.e., the genetic resource). In many cases, an MTA will permit certain R&D on the genetic resources being transferred. The fruits of R&D on the genetic resource under an MTA may, therefore, give rise to intangible property that forms the subject matter of a later license agreement (for example, patents, plant breeders' rights or trade secrets). In this regard, the Organization for Economic Co-operation and Development (hereafter OECD) has promulgated in 2006 guidelines for the licensing of genetic inventions, which provides advice to, *inter alia*, developing countries on how to negotiate licenses.[302]

Sample MTA contracts can be found at the websites for the Secretariat of the CBD (http://www.cbd.int/abs/resources/contracts.shtml), which provides model agreements from Argentina, Australia and Switzerland; the WHO's SMTAs under the Pandemic Influenza Preparedness Framework (http://whqlibdoc.who.int/publications/2011/9789241503082_eng.pdf); and the ITPGRFA SMTA (http://pgrc3.agr.gc.ca/itpgrfa/smta_e.html). In this regard, the NGO Biodiversity International has developed a guide to the ITPGRFA SMTA, which is available online.[303] The SMTAs will need to be used for transfers of genetic resources under the ITPGRFA or in the context of the WHO network for the sharing of pandemic virus samples, respectively. The WHO and ITPGRFA SMTAs are included in Annexes II and III of this handbook, respectively.

One final note is that provisions contained in a typical MTA may also form part of larger agreements intended for joint R&D activity, or where permission is granted to locate biological material within a specified area and to extract it for research. Such provisions are contained in so-called *'bioprospecting' agreements* where, according to the definition utilized by the Association of Southeast Asian Nations (hereafter ASEAN), the user is permitted to access territory of the provider in order to search for wild species with genes that produce better crops and medicines, or the exploration of biodiversity for commercially valuable genetic and biological resources.[304] The bioprospecting agreement is in essence a permit to look for and remove a defined set of biological

[301] *Ibid.*
[302] http://www.oecd.org/dataoecd/39/38/36198812.pdf.
[303] http://www.bioversityinternational.org/training/training_materials/international_treaty/treaty_module.html.
[304] See the draft text of the ASEAN Framework Agreement on Access to Biological and Genetic Resources (2000).

resources in a defined area under the jurisdiction of the permit giver. It can be used as evidence of PIC, but for purposes of this chapter, the terms and conditions on such contracts for extracting and transferring a resource also needs to cover the subjects delineated in this chapter.

Key Points

⇒ MTAs do not envisage the transfer of ownership despite the physical transfer of the genetic resource. In this regard, they are closer and more similar to licenses and loan agreements, than to sales contracts.

⇒ Typical provisions that are contained in MTAs are also found in joint research agreements and bioprospecting agreements, where the user is permitted to access territory of the provider in order to search for wild species with genes that produce better crops and medicines, or the exploration of biodiversity for commercially valuable genetic and biological resources.

III. Substantive Provisions of MTAs with IP Implications

A. Parties to the Agreement

As noted above, an MTA is concluded between a provider and a user. In contracts, only an authorized representative is empowered to enter into obligations that bind the respective provider and user institution. Negotiators should ensure that the person negotiating and signing the contract has the authority to do so.

It is relatively easy to determine the user in question, whether this is a research institution, a zoo, botanical garden or the like. On the other hand, the provider institution may be more difficult to determine. For genetic resources that are linked to practices by a local or indigenous group, especially in the absence of national ABS/TK legislation, it may not be clear whether the group or the national government will have the authority to enter into the contract. While the Nagoya Protocol establishes three cases of ownership giving rise to certain rights (giving PIC and negotiating MAT): first, genetic resources of the State; second, genetic resources of ILCs; and third, associated TK of indigenous and local communities, national legislation is needed to ensure that these rights can be operationalized and enforced. Where there is a question as to the ability of, for example, a provider government institution to authorize the transfer of a resource that is found in territory on which a ILC lives, it is likely that a user will want some assurance that the State has the requisite authority to execute the MTA. The user may want to see that the government institution has been provided with authorization to negotiate on their behalf (for example, through a power of attorney), or that some underlying law grants to the government institution this authority.

Ascertaining the provider of record is important from an IP perspective because if benefit sharing includes joint ownership over any IP or the payment of a proportion of the royalties in the event that the fruits of R&D over the genetic resource transferred gives rise to patent or other IP rights, the party to whom those benefit accrue need to be sufficiently established under the MTA. Depending upon what the national legislation stipulates, it may be possible for the government ABS authority to negotiate and execute the contract, but to ensure that payment goes to a representative indigenous group in the event that the MTA covers subject matter that originates on land held by that group.

Key Points

⇒ The parties to an MTA need to be firmly established. The provider of record is important from an IP perspective because benefit sharing could include joint ownership over any IP or the payment of a proportion of the royalties in the event that the fruits of R&D over the genetic resource transferred give rise to patent or other IP rights.

⇒ For genetic resources that are linked to practices by an ILC, especially in the absence of national ABS/TK legislation, it may not be clear whether the group or the national government will have the authority to enter into the contract.

B. Description and Treatment of the Subject Matter

In a typical MTA, the underlying genetic resource that is being transferred must be described in a manner that makes it identifiable. Often, the resource being transferred is contained in an annex that contains various specifications. One key difference between an MTA and a bioprospecting agreement is that in the latter, one is not sure of what one is going to find given access, and therefore the specification of the resource being transferred becomes difficult. In such cases, it is necessary, nonetheless, to specify the geographic area which is subject to the bioprospecting, to have an idea as to what the party being granted access is bioprospecting for, and what the bioprospector is allowed to do with any specimens found. Like the description of the genetic resource, this can be contained in an annex to the agreement.

Aside from these general issues, there are certain conditions that can be placed upon the genetic resources being transferred that have an IP implication. A typical restriction on the subject matter being transferred in an MTA is that it grants to the user the ability to conduct R&D using the genetic resource in question. Sometimes, clauses containing this restriction limit R&D to non-commercial research. The model MTA from Argentina contains in the minimum clauses common to all MTAs that "[w]hether provided temporarily or permanently, the material shall be used by the Recipient Institution exclusively for non-commercial research." Similarly, the Swiss model MTA assumes that the transfer is for non-commercial purposes, and if the purpose changes, a new contract will need to be negotiated (Article 7). Other model MTAs, such as the relevant clauses in the Australian model MTAs, affirm the ability of a user to commercialize by obtaining IP rights over the fruits of R&D. The ability to apply for patents and plant variety protection are therefore often restricted through MTAs.

As noted in Chapter 4, it is increasingly difficult to distinguish between commercial and non-commercial research. There is always a risk that courts may deem the research being done to be commercial in nature if the eventual goal is commercialization. At the same time, the MTA could potentially be used as evidence in a dispute that the research being conducted should be considered non-commercial in nature.[305] Of course, if the existing research exception under the patent law was wide and encompassed all scientific research, the question of whether the research is commercial or non-commercial becomes moot.

[305] Chapter 3 notes that the existence of a research exception in the patent or plant variety law will not eliminate the need for permission to conduct research under an MTA.

Key Points

⇒ The genetic resource being transferred needs to be described sufficiently in the contract. For bioprospecting agreements, the area made available needs to be specified, what kinds of resources they are looking for, as well as what the bioprospector is allowed to do with any specimens identified and taken.

⇒ Research to be undertaken using the genetic resource that is the subject matter of the MTA may be limited to non-commercial research by contract, even where there is a broad research exception that would permit otherwise.

C. Third Party Transfer

The onward transfer of the underlying genetic resource should be a concern to the provider since the MTA binds only the provider and the user as parties to the contract. This means that a third party to whom the genetic resource is physically transferred by the user may assume that s/he is not bound by any provisions related to IP, including any covenants not to seek IP protection or benefit sharing obligations that involve IP that had restricted the user. The main point for provider countries to keep in mind is that absent a clause in the MTA that prevents the user from transferring the physical genetic resource to a third party, users may do so if they deem it to be in their best interests. As a legal matter, however, users are only able to transfer rights to the genetic resource only to the extent of the rights which s/he has been granted by the provider. This is due to the fact that the MTA is not a contract that envisages the change of ownership of the genetic resource; otherwise the recipient would be able to freely dispose of the resource.

To be safe, provider countries will generally want to include text in an MTA that restricts the user from providing the genetic material to a third party absent the consent of the provider. The model MTA for Argentina states, for example, that "[n]o sample component of genetic heritage, provided temporarily or permanently, shall be released to a third party by the Recipient Institution without the prior execution of a new material transfer agreement between the original provider Institution and the new Recipient Institution. No part of by-product shall be lent or transferred to another researcher or institution without prior written authorization, which shall require a new procedure" (minimum clauses common to all MTAs). The Swiss model MTA provides in Article 8 that the "[t]ransfer of the Genetic Resources for the purposes of academic research and collections, and for training, teaching and education, or any other non-commercial activities is allowed under the condition that the User ensures that the subsequent person or institutions (Third Party) is informed about the provisions under this Agreement and undertakes to pass on the Genetic Resources under the same obligations to any further recipient", including, presumably any PIC and MAT requirements. The WHO system for the sharing of pathogens obliges the User to ensure that any onward transfer of viruses to third parties be based on SMTA1 for entities within the WHO network (Article 5.1.4). The consent of the provider to onward transfer is only granted for entities that are not part of the WHO network if SMTA2 is used (Article 4.3), otherwise there is no authorization for onward transfer and a new agreement must be concluded. The ITPGRFA SMTA obligates the recipient to ensure that onward transfers are made "under the terms and conditions of the Standard Material Transfer Agreement, through a new material transfer agreement" (Article 6.5(a)).

A contractual clause that specifies the rights and obligations of parties in the event that the genetic resource or associated TK is to be transferred thus helps to assure legal certainty for the parties concerned.

Key Points

⇒ As a legal matter, a user will be able to transfer only to the extent of the rights s/he has been granted under the MTA.

⇒ From the perspective of the provider, any subsequent transfer should be subject to the same conditions that the initial transfer was subject to, which include PIC and MAT. Otherwise, the provider is opening the door to potential misappropriation.

D. Intellectual Property Rights

MTAs will differ in how IP rights, such as patents and plant breeders' rights, related to the subject matter material will be treated. At one end of the spectrum, the MTA can prohibit the user from obtaining any IP rights on the material, as in the case of WHO's SMTA 1 (Article 6.1). This presumably would include a prohibition on the user from seeking patent protection on gene sequences and other parts of pathogens covered by the SMTA. The public health interest in securing the greatest possible access to a pathogen for which a vaccine is being sought may help to explain the restrictive language in this SMTA. It should be noted, however, that this language may not prevent the patenting of a vaccine derived from the pathogenic material, as the contractual text limits itself to IPRs over only the material itself. In any event, provider countries may not wish to prevent the outright possibility to obtain IPRs over the subject matter, since it can be assumed that the material is being transferred because the user is in a better position to conduct R&D with the genetic resource than the provider, and therefore more likely to find a way to develop and commercialize the material being transferred. A blanket prohibition on seeking IPRs by the user over products and processes that contain or utilize the material would effectively mean that the contract is precluding a way for the provider to secure any benefits.

Other MTAs therefore leave open the possibility for the user to commercialize via IPRs or otherwise products/processes that contain the material, or are derived therefrom. In this regard, commercialization may not necessarily be through the application for IPRs, as many cosmetic and nutraceutical products are brought to market without IPR protection. The question then becomes one of benefit sharing, and here there are numerous possible variations. Argentina's model CBD MTAs generally stipulate, for example, that the Government of Argentina exclusively retains all IPRs related to the material used and its derivatives. It is unlikely that a user would find such term acceptable, however, since this would effectively prevent him or her from using the IPR to recoup costs related to the underlying R&D. At the other end is the Australian model MTAs for the CBD, which grants to the user IPRs arising from R&D activity using the material (Article 5.2.). Under the Swiss model agreement, if commercialization is sought of the fruits of R&D, new PIC and MAT have to be negotiated (Article 14 and Option 15.3), and the user has the opportunity to file an application for an IPR within an agreed amount of time, after which the provider exercises his or her right to publish the research, thereby placing it in the public domain (Option 15.4). The Annex to the Nagoya Protocol also contemplates the possibility of joint ownership of relevant IPRs (Annex 1(j)).

Beyond the issue of ownership, there are other means by which IPR benefits can be shared. A proportion of the royalties or sales from the commercialization of a product (including through IPRs) can be used to share benefits. This is the model adopted by the SMTA for the ITPGRFA, which states in Article 6.7 that "[i]n the case that the Recipient commercializes a Product that is a plant genetic resource for food and agriculture and that incorporates Material as referred to in Article 3 of this Agreement, and where such Product is not available without restriction to others for further research and breeding, the Recipient shall pay a fixed percentage of the Sales of the commercialized Product into the mechanism established by the Governing Body for this purpose, in accordance with Appendix 2 to this Agreement." The Annex to the Nagoya Protocol stipulates the possibility of royalty payments in respect of relevant IPRs (Annex 1(d)) as a possible means of benefit sharing.

Key Points

⇒ MTAs may prohibit the application by the user of IP rights. At the same time, in so doing, the provider would be foreclosing a possibility of benefiting commercially.

⇒ There are a variety of means to share in benefits from IP rights obtained over the fruits of R&D utilizing the genetic resource in question. These include possible joint ownership of any IP rights, a percentage of the sales of the commercialized product, priority access to the product developed, etc.

E. Benefit Sharing

Benefit sharing as defined by the Nagoya Protocol is directed to the provider. As noted above, IPRs may be a means of benefit sharing, but there is clearly no direct link or obligation in the Nagoya Protocol that requires that IPRs serve the purpose of benefit sharing. Thus, cash flows directly related to IPRs such as royalties or through joint ownership of IPRs is by no means the only way by which there can be benefit sharing under the Nagoya Protocol. In fact, the Protocol lists a number of means to share in the benefits if a product is commercialized from resources accessed under the CBD. The Annex to the Protocol divides, in non-mutually exhaustive lists, benefits into monetary and non-monetary categories. Examples of the former, aside from joint ownership and license fees, milestone payments, special fees to be paid to trust funds supporting conservation and sustainable use of biodiversity, research funding and access fees. Examples of the latter include sharing of R&D results, collaboration, cooperation and contribution in scientific R&D (particularly in biotechnology and where possible in the party providing genetic resources), access to databases, education and training, food and livelihood security benefits, as well as various forms of technology transfer.

While these monetary and non-monetary sharing of benefits may be the subject of a separate agreement, they are often equally built into the underlying MTA. For example, WHO's SMTA2 requires the recipient of a pathogen to either donate at least 10% of real time pandemic vaccine production to WHO, or to make it available at affordable prices to WHO, and/or to donate or make available at an affordable price an unspecified number of treatment courses of needed antiviral medicine for the pandemic to WHO. SMTA2 also leaves open the possibility of granting a sub-license to WHO (Article 4). The ITPGRFA SMTA requires the payment of a fixed percentage of the sale of the commercialized product into a trust fund that supports R&D projects for new plant varieties that are designed to benefit developing countries (Article 6.7). The Australian model

MTA contains a schedule that lists the benefits, including a schedule for threshold payments (Schedule 3). One of the model MTAs from Argentina is designed as a joint research collaboration agreement (Model 2).

From the perspective of the provider of a resource, two general negotiation principles should be kept in mind. The first is that the more restrictive the conditions attached to access, the more limited will be the benefits that a user is going to be willing to provide. The Argentinian model MTAs, for example, stipulate that any IP rights arising from R&D related to the material used and its derivatives belong to the Government of Argentina. Users are likely to argue that the provider has already received a fair deal in the event of commercialization, and may be reluctant to consider other possible benefits. The second is that it will be more the exception that a resource transferred may end up being commercialized. Monetary benefits would, in such case, be illusory. In that case, at least one author argues that developing country providers are better off placing emphasis on opportunities for technology transfer.[306] Given the high risk nature of bioprospecting and the low success rate of finding and developing a genetic resource that can be commercialized[307], users may often be quite willing to spread this risk with joint collaborative R&D. The wide range of possible benefits needs to be assessed when negotiating an MTA, with a view to reaching a satisfactory conclusion acceptable to both the provider and the user. These non-IP benefits need to be strategically considered alongside IP-related benefits.

Key Points

⇒ The Annex to the Nagoya Protocol divides, in non-exhaustive lists, benefits into monetary and non-monetary. Examples of the former, aside from joint ownership and license fees, are milestone payments, special fees to be paid to trust funds supporting conservation and sustainable use of biodiversity, research funding and access fees. Examples of the latter include the sharing of R&D results, collaborative research, training and strengthening capacities in technology transfer, among others.

⇒ From the perspective of the provider of a resource, two general negotiation principles should be kept in mind. The first is that the more restrictive the conditions attached to access, the more limited will be the benefits that a user is going to be willing to provide. The second is that it will be more the exception than the rule that a resource transferred may end up being commercialized, and that any profits will be generated from development.

⇒ The wide range of possible benefits needs to be assessed when negotiating an MTA, with a view to reaching a satisfactory conclusion acceptable to both the provider and the user. Since it is hard to foresee the potential of a candidate resource, non-IP benefits need to be strategically considered alongside IP-related benefits.

F. Jurisdiction and Dispute Settlement

Jurisdiction refers to which set of laws will govern the interpretation of contractual terms and will be applied in the event of a dispute. While in some respects contract law will have some common

[306] Morioka (2009), Chapter 6.

[307] See the example of Japanese pharmaceutical firm Eisai Co., Ltd.'s venture to commercialize products from biological resources in Indonesia in the Indonesia case study found in UNCTAD (2011a). The venture was discontinued due to the inability to commercialize products from samples taken from bioprospecting.

elements from country to country, laws can and do differ substantively, as well as in how judges in the country may interpret certain contractual terms. It is beyond the scope of this handbook to discuss such differences, however. In the context of negotiating a contract across borders, parties will need to assess whether the designation of a certain jurisdiction as controlling law will be more or less advantageous to their interests. Generally, in the context of an MTA, the choice will be whether the controlling law will be that of the provider country or that of the user country.

The question of what happens in the event of a dispute is made even more important because the location of the arbiter of a dispute may have an impact on the provider's ability to access the justice system. If the arbiter is to be the domestic courts, developed countries tend to argue that developing country courts are unreliable and unfamiliar with IP issues. If the provider agrees to the designation of a foreign court of law to resolve disputes that cannot be settled amicably, then the provider may be forced to defend him or herself at great expense in a foreign and often distant court of law, and subject to their civil procedure rules which may be disadvantageous (such as a rule that requires all filings to be submitted in a language foreign to the provider).

Some contracts will call for arbitration in the event of a dispute. Arbitration is basically a private, professional court. Recourse to arbitration may be binding (mandatory) or non-binding. The idea behind the choice of arbitration as a dispute resolution forum is generally that it is private and that it tends to be quicker than a court of law. As mentioned above, one argument used by parties in developed countries is that the courts in developing countries do not necessarily have the capacity to adjudicate on technical cases. Arbitration venues may be located anywhere in the world. The choice of arbitration forum will also determine the choice of applicable procedural rules.

It is acknowledged that courts in many developing countries will not have sufficient expertise to address a case on IP, PIC and/or MAT. Article 18(a) of the Nagoya Protocol recognizes this and obliges each Party to take effective measures regarding access to justice.[308] This may not hold true for all developing countries, though, and a case-by-case consideration is required. From the perspective of the developing country provider, the distance issue could potentially be addressed by choosing an arbitration forum close to home and applying provider country laws as the law governing the underlying MTA. Furthermore, a check to ensure that arbitration does not favor one party over another is to require a panel of arbiters, where one is nominated by the user, one by the provider and a third by mutual agreement. These choices would not, however, address the question of whether there would be a strategic advantage in having the relevant dispute proceedings subject to public scrutiny.

Key Points

⇒ In the context of an MTA, the choice will be whether the controlling law will generally be either that of the provider country or that of the user country.

⇒ Indigenous groups and other rights holders in many poorer countries will often have difficulty when having to litigate to preserve their rights in a foreign jurisdiction. At the same time, users may point out the limitations of some jurisdictions in hearing cases related to IP, PIC and MAT.

[308] A proposal was put forth in the Nagoya Protocol negotiations for the creation of an informal dispute resolution mechanism calling for an 'ombudsman', but this proposal was not adopted in the final text.

⇒ Arbitration is one option which allows parties to tailor make a solution with respect to venue. Part of the issue of having to litigate in distant jurisdictions may be addressed by choosing an arbitration forum closer to home.

⇒ Recourse to private arbitration may take a case out of public scrutiny, to the extent that litigation in the courts is a public process where documents are often available for all to see.

G. Term/Duration of the Agreement

The duration of the agreement establishes the length of time for which the parties are bound by the contract. Samples of genetic material transferred under an MTA may be transferred temporarily (loaned) or permanently. If the genetic material is to be transferred temporarily, then the contract should stipulate for how long the material is to be loaned to the user, and this will often determine the duration of the contract. This is the case when an animal is loaned to a zoo, for example.

Genetic material can also be transferred permanently, for example in the case of certain cell samples. In such cases, it makes little sense to ask for the original sample back after a certain period of time, as the sample is being given to a user who intends to cultivate the cell and perform R&D on it. The term of the contract will, however, often be shorter than the perpetuity that the permanent transfer implies. In such cases, providers will want to ensure that certain commitments entered into in respect of the material transferred survive beyond the duration of the contract (i.e., Argentina's model MTA no. 3, paragraph 9). These may include covenants not to seek IPRs or benefit sharing that arises out of IPRs, for example. In some jurisdictions, courts will interpret whether the restrictions that survive the end of a contract are reasonable.

In other cases, the contract may provide that the resource be destroyed if an MTA is terminated for default or cancellation of permit, as in the model Australian MTA (Article 13.4.1.b). While practical for certain resources such as virus samples, this may not be practical or ethical in the case of endangered species.

The term of a contract may be renewed. In such cases, the renewal should also stipulate that PIC and MAT continue to be met.

Key Points

⇒ Resources may be transferred under an MTA temporarily or permanently.

⇒ The term of an MTA contract will often be shorter than the perpetuity that the permanent transfer implies. In such cases, providers will want to ensure that commitments entered into in respect of the material transferred survive beyond the duration of the contract.

⇒ A contract may provide that the resource be destroyed at the end of a contract term. While practical for certain resources such as virus samples, this may not be practical or ethical in the case of certain animal or plant species.

H. Termination

Termination refers to the end of the agreement. A good deal of thought needs to be given to what will trigger the termination of the agreement, and what the consequences of that will be.
Generally, contracts may be terminated voluntarily or mandatorily through the occurrence of an event. In the case of voluntary termination, parties may agree on a period of time to give written notice of termination, such as three months. Generally, there is no legal requirement for the time required to be give notice of termination to be equal for both parties to a private contract, beyond a general standard of reasonability.

Contracts may also be terminated involuntarily. The cases where the contract is terminated involuntarily must, however, be clearly spelt out in the MTA, otherwise the contract may be deemed by courts to continue to remain in force. A particular case that providers should be aware of is the potential for *insolvency*. Insolvency refers to the situation where a person either has ceased to pay debts or meet their contractual obligations in the ordinary course of business or cannot pay debts as they fall due, or is otherwise bankrupt under the national insolvency law of the country of the user.[309] Biotechnology firms are often engaged in high risk activity, and consequently face a potential risk of insolvency. If a user firm defaults and becomes insolvent, a trustee may assign user assets to other parties to whom the provider never intended. This may include the genetic resource transferred, reproductions of that genetic resource, products or variants derived from that genetic resource as well as any IPRs that the user had sought and obtained over any of these.

It is clear that in the case of insolvency, it is possible to stipulate in the MTA that the actual genetic resource transferred be returned to the provider. This would provide a clear instruction to the trustee in bankruptcy on the disposition of the genetic resource in question. At the other end of the spectrum, the IPR is an intangible asset of the defaulting user. The trustee is therefore at liberty to dispose of this in settlement of debts, and the IPR could end up with an unintended user. One possible defense from the perspective of the provider is to request when establishing an MTA an inexpensive (or cost-free) irrevocable license for any IPRs obtained by the user using the transferred genetic resources, as part of the benefit sharing package. Another option would be to agree at the outset that any IPRs over the fruits of R&D would be jointly owned by the provider and the user, and that any disposal thereof would require the agreement of both parties.

The most difficult question concerns what to do with reproductions of that genetic resource, or with variants or products derived from that genetic resource that represent R&D in progress, but not yet at a stage where they can be embodied in a registered IPR. From a strictly defensive position, one could obligate the user to destroy these in the event of termination, as in the case of the Australian model MTA (see section above). While this would presumably prevent the work in progress from falling into unintended hands, the disadvantage of this is that the fruits of the R&D are potentially lost.

A contract may also be terminated if there is a material breach of the agreement that cannot be cured. What constitutes a material breach can be defined by the parties. If, for example, the MTA stipulates that the recipient would not seek to obtain IPRs on the genetic materials provided, a user who sought and obtained patent protection over the material could be deemed in material violation of the contract. In order to be sure that such act would be treated as a material violation, the parties may expressly stipulate this in the MTA. If the contract does not stipulate what a material breach is,

[309] This definition borrows from the definition contained the Uniform Commercial Code of the United States.

a court may decide on the question of whether a deviation from the contractual obligations constitutes such a breach, and whether that breach warrants termination or damages. In other words, there is no guarantee that, in the absence of a clear written indication, a covenant to refrain from seeking IPRs on the genetic materials provided would be considered a serious breach.

Key Points

⇒ Contracts may be terminated voluntarily or mandatorily through the occurrence of an event. The cases where the contract is terminated involuntarily must, however, be clearly spelt out in the MTA, otherwise the contract may be deemed by courts to continue to remain in force.

⇒ If a user firm defaults and becomes insolvent, a trustee may assign user assets to other parties to whom the provider never intended. This may include the genetic resource transferred, reproductions of that genetic resource, products or variants derived from that genetic resource as well as any IPRs that the user had sought and obtained over any of these. The termination clause should give the trustee guidance in such cases.

⇒ There is no guarantee that, in the absence of a clear written indication in the MTA, a covenant to refrain from seeking IPRs on the genetic materials provided would be considered a serious breach.

I. Confidential Information

Firms that seek to access genetic resources and related traditional knowledge for the purpose of eventual commercialization of a product developed from that resource seek to maintain as much of a competitive advantage over potential rivals as possible. Many of these firms bring R&D and related know-how to bear on the resource for possible development, and generate data from experiments which they may seek to keep secret from their rivals. For this reason, many MTAs will include in a schedule or annex information which the parties to the contract oblige to keep confidential (see, for example, the model Australian MTA).

From a legal point of view, there is nothing that prevents the designation of certain information as confidential in a private contract, or even to treat the entire MTA contract as confidential provided both parties agree to it. The TRIPS Agreement, in Article 39, ensures that WTO Members shall protect undisclosed information and data submitted to governments or its agencies. The Nagoya Protocol places no limits on what can be treated as confidential in a private contract, subject, however, to the limitation that national regulatory authorities may require the submission of the underlying contract in order to obtain a national (and international) certificate of compliance. The regulatory authorities concerned are obliged in such case to maintain the confidentiality of the information designated as such by the underlying contract. Articles 14 and 17(a)(iii) of the Protocol stipulate that information that is submitted to the ABS Clearing House shall be "without prejudice to the protection of confidential information". Article 17(4) provides that the internationally recognized certificate of compliance shall contain the following minimum information when it is not confidential:

(a) issuing authority;

(b) date of issuance;

(c) the provider;

(d) unique identifier of the certificate;

(e) the person or entity to whom prior informed consent was granted;

(f) subject matter or genetic resources covered by the certificate;

(g) confirmation that mutually agreed terms were established;

(h) confirmation that prior informed consent was obtained; and

(i) commercial and/or non-commercial use

In this regard, if it was hoped that outside groups and checkpoints could monitor the implementation of the ABS rules against misappropriation, in practice the certificate system's actual value may be limited to certifying that, in the view of the national competent authority, PIC and MAT have been complied with. From a public policy perspective, providers may want to resist demands to treat the entire MTA contract as confidential and insist that at least those items contained in Article 17(4) of the Protocol above remain non-confidential in order to facilitate monitoring.[310] National legislation on the right to access environmental information, if it exists at all, may help support this position in certain circumstances.

Key Points

⇒ The Nagoya Protocol places no limits on what can be treated as confidential in a private contract.

⇒ From a public policy perspective, providers may wish to resist demands to treat the entire MTA contract as confidential and insist that at least those items contained in Article 17(4) of the Protocol above remain non-confidential.

IV. Conclusion

IP and ABS are regulatory functions, but ultimately both these systems rely heavily on private law for their actual implementation. Key terms in ABS agreements will therefore be important means to secure the rights of the provider in any given situation where access is being considered. Those negotiating such contracts need to be aware of the meaning of these provisions in order to ensure that the contract does not unwillingly permit or lead to misappropriation or other unintended consequences. As much as knowledge of the law is important, so are the negotiating skills of the provider.

[310] It should be noted that Article 21(6) of the Cartagena Protocol significantly limits the range of confidentiality, but a similar text was not adopted in the final text of the Nagoya Protocol.