TECHNOLOGY TRANSFER AGREEMENTS AND THEIR IMPORTANCE

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INTRODUCTION

One would conclude from all of the advice given on technology transfers in the various workshops and panel discussions of meetings such as the present one that the basic do's et don'ts of technology transfers are known to the Biotechnology Industry. Furthermore, literature containing precedents in the field of technology transfer abounds.

However, being aware and understanding the importance of protecting technology transfers by contract and having knowledge of the ideal contents of such contracts does not necessarily guarantee their consistent use.

WHY TECHNOLOGY TRANSFER AGREEMENTS ARE OFTEN OVERLOOKED

It is fair to presume that the spirit of collegiality amongst scientific researchers and the principle of the free mouvement and exchange of ideas in the field of scientific research, runs contrary to the element of distrust which seems to be inherent in the contractual arrangements proposed to these researchers by their legal advisers from time to time.

Further, the reticence to consistently conclude such agreements resides in the difficulty of delineating the rights that are to be transferred. This may be said to be the legal profession's "needle-in-a-haystack" problem which existed in the biological research field prior to the development of techniques that

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allow for the identification and isolation of compounds found in minute quantities in living organisms.

Briefly put, attempting to delineate the actual transfer and finding what the intent of the parties is in such contracts, can be laborious enough in itself to discourage recourse to certain contractual arrangements and prompt the parties to carry out their inter-action of an informal basis.

It is suggested that it is not so much the eventual content of a technology transfer agreement that poses a problem in this field. When problems do arise, it is when the parties to a transfer do not as a matter of course and a matter of practice automatically proceed to a written exchange on the various elements of the transfer. As we shall see later, such oversights can become very costly and jeopardize years of hard work and even, ultimately cause society to lose the benefits of the practical application of the technology involved or at least slow down such advances.

THE TRANS-NATIONAL CONTEXT

Common sense dictates that it should be even more evident that the parties involved in a technology transfer set out the terms of the transfer in writing when it is carried out in a trans-national context. In such cases, it is obvious that the importance of questions of alternative dispute resolution systems, legal forum for disputes, and applicable law for dispute resolution, become magnified.

Furthermore, it is not uncommon in the biotechnology field that a transfer which commenced between two parties evolves to include more players. When the transfer is carried out overseas and the situation evolves in this way it is important that each player abide by the same set of rules. In such situations it is therefore important that the owner of the technology retain control over it and ensure different parties are not entitled, for example, to sue each other with respect to any dispute in different jurisdictions.

Prior to continuing on this question of control, we wish to discuss the oft forgotten methods by which technology may be transferred. It is especially true in trans-national technology transfers that the parties ought not to rely only on transfers by way of license.

THE IMPORTANCE OF NON-LICENSING TECHNOLOGY TRANSFERS

Furthermore, the practice of overly focusing on patent rights and evaluating only the patent rights being transferred should not be blindly followed.

Licensing is but one manner in which entities may carry out a transfer of technology. Confidential information relating to processes, know-how, and trade secrets all form part of the patrimony of a company in the same way that a patented invention does. In the biotechnology field, transfers are often made at a point in time when patent protection is not even available given the rudimentary stage of the research involved or the lack of a practical application for it. As long as a company's information is secret and has not been divulged and become part of the public domain it is an asset, albeit intangible. There are many instances where non-licensing technology transfers, and transfers of technology, that is property, which is not patented, are the more appropriate vehicles. These agreements can take the form of confidentiality agreements, know-how agreements, turn-key agreements and even joint-venture agreements, amongst others.

These various types of arrangements allow a company that is not present in the country where the technology has been transferred to nevertheless exercise greater control over its property. This may be contrasted with cases where technology is simply transferred by license to wholly-owned subsidiaries in foreign countries. Subsidiaries are subject to political change which may occur in the country in which they operate. The European common market is no different in that the regulations of the union in matters of competition and intellectual property are in constant flux.

We wish to conclude on this point by stating that in any technology transfer situation, especially in a trans-national situation with a party residing in Europe or elsewhere, and depending on the technology involved and the degree to which it has evolved, one must always consider the advantages of contractual technology transfer over that of simple licensing.

Even the EEC has been known to provide for the liability of a licensor for damages caused as a result of defects in the product under license. These contracts are no more limited in their scope than standard licensing agreements. Time-tables with respect to various development stages may be stipulated in such a contract. The choice of forum, applicable law and even alternative dispute resolution methods may be included in contractual technology transfers, whether or not the property transferred is patented.

A NOTE ON DOING BUSINESS WITH EUROPEAN ENTITIES

In the present paper we are of course concerned mainly with trans-national technology transfers with a slight emphasis on Europe. No one doubts the importance of the emerging European market in the intellectual property field. It is said that the European market has a population of approximately 700,000,000 people and is responsible for 40% of the world gross national

product. Experts in the licensing field estimate that the North American licensing market is no longer growing. This is in stark contrast with the situation in Europe. It is likely that North American companies, whether in the biotechnology field or otherwise, will develop a European licensing strategy based on the premise that Europe is one market as opposed to a collection of several different markets established on a country-by-country evaluation.

It is suggested that Europeans are much less litigation oriented than we are in North America. Furthermore, in our experience, we may state that in the legal field, Europeans tend to be less formalistic in their business dealings than us. These two cultural differences (which are not necessarily flattering with respect to our North American business culture) are nonetheless important considerations in any technology transfer situation. One must clearly explain to a European counterpart the importance of documenting every element of each transfer which occurs between parties. One must explain and make clear to the European counterpart the readiness with which North American businesses will resort to legal proceedings in the event of a dispute and to ensure they understand that alternative dispute resolution remains, to date, the exception rather than the rule in everyday practice in North America.

Apart from these cultural considerations, it is also important to keep in mind when dealing with a situation where the technology is transferred to Europe that recourse must be made to local counsel or at very least counsel familiar with EC regulations and local intellectual property laws.

For example, the Commission of the European Communities has, in the past, promulgated lengthy regulations with respect to the application of Article 85(3) of the treaty establishing the European economic community. Article 85(3) is, of course, the anti-combines provision of the treaty. The EC has decided to specifically regulate know-how agreements and basically the transfer of known patented technical information, whether they be pure know-how, licensing agreements or mixed, know-how and patent licensing agreements.

Furthermore, the European counterpart to a North American European technology transfer may be an agent of the EC or may be an entity sponsored by one of the EC's sub-commissions. In such cases, the Commission of the European Communities may foresee, in its regulations, specific controls relating to the technology which results from the commission's financial participation in the research of one of its agents or even a private company which it sponsors and which could be the company which the North American party is dealing with. It is, therefore, always advisable to verify the corporate make-up of one's co-contractant party and to establish whether it has benefited from EC financing or whether it is in fact an agent of the Commission.

In looking at all of these complicated issues, one is sometimes attempted to overlook a very obvious question and that is the basic comprehension of negotiations. It is suggested that European companies dealing in a North American market obtain counsel that can offer their services in the language understood by the principals of the European company. North American companies should also, in any negotiation, be assisted by persons who speak the language of their counterparts in order to ensure a maximum of understanding between the parties at the outset of negotiations and in the highly technical descriptions of the technology being transferred.

DELINEATING THE OBJECT OF THE TRANSFER

Whether one proceeds contractually or through a licensing agreement, and whether the technology is patented or not, it is always vital that the parties have a clear understanding of what the technology is that is being transferred. Biotechnology transfers are particulary challenging when it comes to delineating the object of a license or contractual transfer. Again, it should be remembered that the transfer of patent rights should not blind parties to technology transfers from other types or arrangements, since what is often being provided to the receiver of the technology is a "head start" in the manufacture of new products and a tool which allows it to penetrate new markets.

On the subject of markets, it is important to remember that large European corporations do not, as is sometimes the case in North America, denigrate the role of licensee or receiver of a transfer of technology. Furthermore, once these corporations do decide to make a move in the technology transfer field, they have usually settled patent and regulatory questions before concluding a transfer such that they are ready to attack the market upon the conclusion of the contract.

In technology transfer agreements, the licensor should always retain litigation rights. Furthermore, it is always advantageous to ensure local imput into the process especially as it concerns taxation, legal and accounting questions.

ABSOLUTE NOVELTY REQUIREMENTS

Notwithstanding what we have been asserting thus far, it is evident that patent rights are a crucial element of technology transfers. One of the most important notions to keep in mind when transferring technology in the European context is the absolute novelty rule generally applicable in European patent law. Contrary to Canada and the United States, an

invention cannot under any circumstances be disclosed before the filing date of the application. Disclosure can range from anything from advertising the product in a way that reveals the invention, displaying a product at a trade show, or even telling friends about the product. In Canada and in the United States there is a twelve-month grace period for such disclosures. We wish to add that each country in Europe may adopt exceptions to this rule such as is the case in France where divulgation at certain specifically designated trade shows will not automatically result in a loss of patent protection.

Showing a product to a potential investor with a confidentiality agreement is, in principle, not considered to be a public disclosure. As such, the technology transfer agreement or confidentiality agreement is not normally considered to be a public disclosure. However, if the person to whom the disclosure is made in confidence violates that agreement (and one can never fully defend oneself from such an occurence) the invention can be said to have become publically disclosed and excluded by the absolute novelty rule, where applicable.

Prudence dictates that when one wishes to transfer technology at a point of time when it consists of a patentable invention, that one apply for the patent in the event Europe consists of a potential market for the final product. The absolute novelty requirement is strictly enforced in Europe. The disclosure need not be in any particular European country: for it to become a bar to patent registration, public disclosure can occur in Canada, for example, and operate as a bar to filing in Germany.

CASE STUDY: WHAT CAN GO WRONG

Practical examples of what can go wrong when the parties to a technology transfer have neglected to proceed with contractual arrangements or license agreements for both patented and unpatented technology may be illustrated by a case of which I am particularly aware of.

There are two Defendants in this case, one Defendant is the owner of a patent for an invention which relates to means and methods for the diagnosis of lymphadenopathy and acquired immune deficency syndrome (AIDS). This patent contains claims for the practical application of the invention. These claims describe an HIV-1 diagnostic kit for the detection of the presence or absence of anbodies which bind to antigens of human retrovirus indicative of acquired immune deficency syndrome.

This Defendant is also the owner of a patent application which relates to an HIV-2 detection kit.

The co-Defendant is the world-wide licensee of the patent owner domiciled in an EC country. The patent owner is domiciled in the same country and is one of the biggest and most important entities in the world in the research field. Its world-wide licensee carries out the commercial activities relating to the technology of the patent owner, not only with respect to the patent and application in the present case but for all of the discoveries of the patent owner.

The Plaintiff is a large North American publically traded biotechnology company.

Plaintiff alleges that technology transfers were made on a regular basis between it and the world-wide licensee of the patent owner over a period of approximately eighteen months.

More specifically, Plaintiff alleges that it had developed certain synthetic peptides which allow it to create an HIV-1 and HIV-2 detection kits. Its main claim in its action is that its own kit is the most efficient on the market and that its margin of error is substantially lower than all other such kits on the world market.

To commence with, according to Plaintiff, the parties exchanged whatever patents or patent applications they had in the relevant field of HIV detection. Plaitiff claims in its action that it was concerned that some of the fruit of its research may be "caught" by the inventions taught in Defendants' HIV-1 patent and perhaps eventually in its HIV-2 patent application. It also claims, however, that the co-Defendant, the licensee, showed some interest in the synthetic peptides used by the Plaintiff in its HIV-1 and HIV-2 detection kits.

Briefly put, Plaintiff claims that at the time it commenced dealing with the co-Defendant it had perfected cyclical synthetic peptides which allowed for a very efficient detention of HIV-1 and HIV-2.

According to the Plaintiff, the licensee of the patent holder wished to proceed to a comparative study of the immuno-reactivity of the synthetic peptides created by the Plaintiff and requested samples of those peptides as well as technical information in order to allow it to effectuate its analysis.

Plaintiff alleges that shortly thereafter it forwarded to the licensee twelve coated plates containing the peptides in order to allow the master-licensee to carry out its tests. According to the Plaintiff, the coated plates and their contents were not available to anyone else in the market place.

Plaintiff also contends that the licensee, approximately one month later, requested further samples, but this time, of free peptides.

This demand was allegedly adhered to. None of these transfers were covered by a contractual arrangement or a license. At that point, it appears that all negotiations were verbal. It is only after these two transfers were carried out that the parties discussed the possibility of a future sub-license between the Plaintiff and the licensee. Evidently, the Plaintiff was worried that its technology, although it might have been enhancing, infringed upon Defendants' patent rights and may have consisted of an infringement of the patent application for the HIV-2 detection kit, eventually to be granted.

After the two previously mentioned transfers, negotiations allegedly ensued with respect to the question of a potential sub-license, but nothing was ever confirmed in writing. Plaintiff alleges that the licensee demonstrated interest in the peptides transferred and was impressed by their extremely high specificity. A specific peptide was identified by the licensee as being the best performing and, according to the Plaintiff, the licensee requested additional materials in order to continue its analysis of their potential. A third transfer was made at that point. Five or six months later, ten more coated plates were allegedly forwarded to the licensee containing new synthetic cyclical peptides. These peptides are alleged to have been even better performing than all previous ones transferred but again, no contract was signed between the parties and it was still not clear as to whether a license was to intervene between the parties to these exchanges or what its terms would be.

Several months later, according to Plaintiff, the licensee requested even more free peptides and requested information on their coating procedure. Plaintiff alleges that one of its employees personally brought with him to Europe these specifically requested peptides along with the protocol for the coating. Obviously this was highly confidential information but was still not regulated by a contractual arrangement. In its action, the Plaintiff states that it transferred this confidential information because it was made to believe that it would receive a sub-license for the property owned by the patent owner.

Another transfer of technology was made some weeks after that European visit, when three diagnostic kits manufactured by the Plaintiff were allegedly remitted to the licensee along with further information concerning the results obtained with these kits. Again, the Plaintiff alleges that it communicated this confidential information due to the fact that it was made to believe that it was to obtain a sub-license.

Plaintiff alleges that it even acceded to the request of the licensee to use Plaintiff's own laboratories to carry out further tests on the basis that it was led to believe that it would eventually receive a sub-license. Obviously, Plaintiff

contends that a great deal of confidential information was communicated to the licensee during its studies in Plaintiff's laboratory.

We with to point out that Plaintiff's diagnostic kit is a multiple-use diagnostic kit and is not restricted to HIV-1 and HIV-2 detection. As such, the Plaintiff does not even confirm that the parties agreed on the royalty rate to be paid because of the difficulty of attributing the proportional value of the HIV-1 and HIV-2 detection properties of the kit.

Several months after the visit to Plaintiff's laboratory, the Plaintiff forwarded a technical report to the licensee allegedly containing technical information with respect to its various diagnostic kits.

Shortly thereafter the patent holder put the Plaintiff on notice to cease commercialising HIV-1 detection kits, since, in the opinion of the patent owner, these kits infringed upon its patent. According to Plaintiff, this letter coincided with a notice from the licensee to the effect that it did not wish to grant the sub-license sought by the Plaintiff.

In its action, Plaintiff claims that the patent owner ought to be bound by the representations of its licensee. It further alleges that it was led to believe by the licensee that if it freely communicated confidential information and the results of its research, and that an infringement problem was on the horizon, it would receive a sub-license with respect to its technology. Plaintiff has requested declaratory relief from the Court. More specifically, Plaintiff has asked the Court to declare that a sub-license exists between the licensee and the Plaintiff with respect to the patent and the patent application of the patent holder as they concern HIV-1 and HIV-2 detection kits. Furthermore, Plaintiff requests that the Court render a Declaration of non-infringement based on the fact that a license exists. Basically, the Plaintiff is requesting that the Court invoke one of several doctrines in patent law which may be used to exculpate an alleged infringer. These include the notion of tacit license, and consent. Subsidiarily, the Plaintiff is requesting damages in excess of 15 million dollars from both Defendants as compensation for the expenditures it claims it made during its dealings with the Defendants and the damages that resulted from its having been allegedly falsely led to believe it was to receive a sub-license.

LESSONS TO BE LEARNED

No matter what the outcome will be, this case demonstrates the importance of many of the principles that have been discussed and that will be further reviewed during this workshop and indeed in the other workshops, and numerous conferences that have been given on this subject.

We see here that the owner of the patent has lost control in the sense that its licensee's acts are being attributed to it by the Plaintiff. Furthermore, for your information, the licensee has not retained the same counsel as the patent owner.

One of the first pre-trial Motions instituted in this case put in issue the jurisdiction of the Court, as is usually the case when the dispute concerns trans-national activity. Neither the Plaintiff nor the Defendants had foreseen this problem before entering into this fairly long-term relationship. The action was instituted over eight months ago and a defence has still not been filed because of the question of jurisdiction and another pre-trial Motion. Furthermore, the applicable law is not clear on the face of the record.

It appears that the parties in this case have not properly delineated the goals and finality of the technology transfers that occurred. They are also faced with a situation where each side owned patents and rights to patent applications which will perhaps be in conflict. This would have been an ideal situation where express contractual arrangements could have been used to protect both sides from unforeseeable contingencies and the ambiguity of litigation. The business objectives of the parties were not clear and there was no express agreement on who owns what. It appears that Plaintiff's position is to the effect that it was verbally promised some sort of sub-license and based on that promise it forwarded what it now designates as "confidential" information. It is fair to presume that Plaintiff will encounter serious difficulties on this point in this litigation.

The licensee too will suffer from not having clarified its position and stating clearly in writing whether or not it intended to eventually grant a license and to properly delineate the nature of the transfer. The patent owner is the one that is probably most prejudiced because its patent has been placed into question and according to Plaintiff's claim, it had little or no dealings with either of the other two parties. The patent owner is also more or less obliged to get all of its information in this case second-hand.

As mentioned above, written contestations to the action have yet to be filed by the Defendants and will not be for some time. One can safely assume that each party to this action has already paid a great deal in legal fees and disbursements to date, and they have not even past the preliminary Motions stage. This is money that is not being spent on scientific advances, to the detriment, one can say, of society.

CONCLUSION

We trust that our introductory remarks and the foregoing example of a litigation nightmare have impressed upon you the importance of establishing as a question of policy and a matter of course the transfer of technology through either the contractual or licensing vehicle, and then once the appropriate vehicle is chosen seeing to the inclusion of the proper elements, especially when dealing in a trans-national situation.

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