

INTELLECTUAL PROPERTY RIGHTS AND RESEARCH AND DEVELOPMENT CONTRACTS

Introduction

In recent times, foreign companies have shown an avid interest in India for trade in technologies and services and are establishing research and development centers in India, as a result of which intellectual property rights issues have gained significant importance. India, with its traditional systems of medicine, has suddenly shot into the limelight. With the Trade Related Aspects of Intellectual Property Rights (“TRIPS”) treaty, to which India is a signatory, set to become a reality by the year 2005, pharmaceutical companies are gearing up for potential tie-ups in the post TRIPS era.

Pre-Contractual Issues

Definition of Research and Development Contracts (“R&D Contracts”)

In India, there is no specific legal definition of R&D Contracts. Most companies proposing to enter into research and development arrangements term such contracts as R&D Contracts.

Legal Framework of R&D Contracts

Let us assume the following hypothetical scenario for the purpose of this paper.

ABC is an US based pharmaceutical company engaged in the marketing, research and development of pharmaceutical products. ABC is the owner of proprietary technology used in the development and manufacture of drug Z. This process was patented in the US in 1994. ABC proposes to carry on research and development in India on various products by entering into partnership with XYZ.

Apart from the Indian Contract Act, 1872 and the laws as mentioned below, there is no specific legislation in India dealing with R&D Contracts. In respect of R&D Contracts in the area of pharmaceutical or drug research, issues of ownership of research material and export of the strategic research information become important. Certain seeds, plants and traditional Indian herbs cannot be exported out of India. However, the fruits of research and development can be utilised abroad.

The Drugs & Cosmetics Act, 1940 (the “Drugs Act”) and the Drugs and Cosmetics

Rules, 1945 (the “Drugs Rules”) prescribe the standards and quality, and regulate the import, manufacture, sale and distribution of all drugs, including ayurvedic drugs in India. The Drugs Act prescribes a particular standard for manufacturing a drug for sale or for distribution. The drug manufactured should comply with the standards for identity, purity and strength as laid down. Any company proposing to manufacture drugs must take adequate precautions at the time of manufacture to prevent the drug from being categorised as poisonous. In order to commence pre-clinical and/or clinical trials in India of foreign compositions or drugs, the prior permission of the Drugs Controller of India is required. Therefore, R&D Contracts must cover this aspect. The onus must be placed on the Indian R&D company to obtain all the necessary approvals from the office of the Drugs Controller. Note that this process can be lengthy and cumbersome.

If a R&D Contract is accompanied by a technology licensing agreement, prior permission of the Reserve Bank of India (“RBI”) is required. The RBI permits payment of a lump sum licence fee of US\$ 2 million and certain royalties. In case, lump sum fees in excess of this amount are sought to be paid, prior permission of the Secretariat of Industrial Assistance, New Delhi is required.

If ABC seeks to enter into a joint venture agreement with XYZ, prior approval of the Foreign Investment Promotion Board (“FIPB”) or the RBI may be required, depending upon the area of investment. Note that the Government of India guidelines permit ABC to have an equity stake upto 74% in an Indian company. Therefore if ABC and XYZ set up a new entity PQR, ABC would be permitted to hold an equity stake of 74% in PQR. The permissions granted by RBI and FIPB to ABC would be valid for a period of two years. Every six months, a statement is required to be submitted to the Secretariat of Industrial Assistance as regards the status of the project and the amount of money invested. If the parties fail to take steps as per the permission letter, the permission may not be renewed on expiry of the two year period. It would normally be advantageous for ABC to enter into a partnership with a local partner, i.e., XYZ in order to understand the local practices and the opportunities available in the market.

Alternative Ways of Requiring Technology

If ABC and XYZ decide to develop certain technology, then they become exclusive owners of the patent subject to the terms and conditions of the agreement they enter into. Ownership denotes a bundle of rights, i.e., a right of disposition, a right of possession, a right of enjoyment and a right to leave it by will. If ABC and XYZ

decide to gain access to IP rights, then they will not enjoy the rights of ownership. In such an event they will have only rights of possession and enjoyment, while the rights of ownership vest in some other party. Note that a patent right is a property. The patentee has the exclusive right to make, use, sell, exercise or distribute a patented article or use the patented process, by himself or by his agents or licensees. He has the power to assign, grant licences or otherwise deal with the patent right. In an assignment, proprietary rights are transferred, whereas in a licence, they continue with the patentee, only permission is granted to work the patent.

Therefore it would be advisable for ABC and XYZ to develop technology and become the owners of the patent.

Description of IP rights

The law in India relating to intellectual property and to the protection of the rights of its exploitation and use are contained in the Trade Marks Act, 1999 (“TM Act”), Patents Act, 1970 (“Patents Act”) (as amended), Designs Act, 2000, and Copyright Act, 1957 (“Copyright Act”).

Under the Patents Act, ABC can seek protection in respect of its inventions made by it. India is a signatory to the Paris Convention and the Patent Cooperation Treaty (“PCT”). Note, however, that under the Patents Act, certain inventions are not patentable, i.e., inventions that are:

(a) frivolous; (b) contrary to law; (c) relating to mere discovery of scientific principles; (d) a method or process of testing to render a machine or apparatus more efficient; (e) a method of agriculture or horticulture; and (f) any process for the medicinal, surgical, curative or other treatment of human beings, animals or plants to render them free of disease.

As ABC is the owner of proprietary technology, it may want to patent this technology in India. Note that only a “process” for developing a drug is patentable under the Patents Act (section 5 (1) (a) of the Patents Act)

Pursuant to signing the TRIPS treaty, the US has been notified by the Indian Government as a convention country. Under the Patents Act, an inventor, whose patent is registered in a convention country, seeking to register his patent in India can be denied registration if the application is not made within twelve (12) months from the date of the first application for protection made in the convention country (section

25(1)(i) of the Act). In addition, the application can also be denied on the ground that the invention so far as claimed in any claim of the completed specification has been published before the priority date of the claim in any country (section 25(1)(b) of the Act).

Therefore, if the patent has been published in the U.S.A. or if the U.S. Patent Office application has been made prior to twelve (12) months from the date of the first application in India, the Indian Patent Office will not register ABC's U.S. patent in India.

As mentioned above, note that under the Patents Act only the "process" of manufacturing a drug is patentable. However, the actual drug is not patentable. Section 5(a) read with section 2(1) of the Patents Act states that "inventions - claiming substances intended for use, or capable of being used, as food or as medicine or drug, no patent shall be granted in respect of claims for the substances themselves, but claims for the methods or processes of manufacture shall be patentable."

The Patents Act was amended in 1999 to bring it in line with TRIPS. With this amendment, product patent applications for pharmaceutical products in respect of inventions made in India or abroad after January 1, 1995 are required to be accepted by the Indian Patent Office under the mail-box mechanism and exclusive marketing rights ("EMR") must be granted to an applicant who satisfies the prescribed conditions. The EMR provisions in the Act apply only to those inventions in respect of which patent applications have been filed in India or abroad on or after January 1, 1995. Since the drug Z was launched worldwide and was patented in the US, ABC will be able to make an application to patent drug Z in India. In addition, it will also be able to apply for an EMR in respect of drug Z.

Therefore, ABC will be able to apply for EMRs in India in respect of inventions made in India. In addition, ABC can make PCT applications in Calcutta, India and obtain worldwide protection for its new inventions.

Under the TM Act, ABC can protect its trade marks in India under the TM Act by registering them under the prescribed class. The TM Act will be amended to enable registration of service marks, shortly. Registered owners can assign to third parties the right to use the mark and are not mandated to use the marks personally (section 36 of the TM Act). The user agreement must be registered at the office of the Trade Marks Registry. By registering a user agreement, the owner prevents the user from getting a right to be the registered proprietor of the mark through use.

Under the Copyright Act, ABC can protect its manuals containing the entire R&D technique, etc. ABC can avail of civil remedies if any infringement of its copyright takes place which includes injunction, damages and accounts of profits made by the defendant by violating the copyright (section 55 of the Copyright Act). In addition, criminal remedies such as imprisonment for a period between six (6) months and three (3) years are also available. In order to enforce a copyright, Indian courts prefer it to be registered.

Know-how

There is no copyright in ideas or information as such, and accordingly, there is no remedy under the Copyright Act for unauthorised use of confidential ideas or information obtained directly or indirectly by one person from another. The remedy for this lies in tort for breach of confidence or breach of trust. The reliefs that can be obtained are an injunction and damages. It is well settled that information imparted in confidence (especially information which is imparted in confidence to servants and agents) will be protected. Indian courts will restrain the use of it if it is in breach of good faith. The work on this subject does not depend on any implied contract. It depends on the broad principle of equity that he who has received information in confidence shall not take unfair advantage of it. Know-how can also be protected in the foregoing way.

Conditions of Transfer of IP Rights and Technology

The rules of transfer of IP rights are determined by statute as laid down in the Patents Act, TM Act and Copyright Act. If ABC or XYZ propose to transfer their rights, they will be governed by these Acts. There are some conditions which have to be fulfilled before IP rights can be transferred.

Under the Patents Act, the creation of any interest in a patent, including an assignment, mortgage or licence is not valid unless it satisfies the following requirements:

- (1) the assignment, mortgage or licence is reduced to writing in a document embodying all the terms and conditions governing the rights and obligations between the parties;
- (2) an application for registration of such document is filed in the prescribed manner.

The document when registered will have effect from the date of execution. A document in respect of which no entry has been made in the register will not be admitted by the Controller or by the court as evidence of title of any person to a patent unless the Controller or the court directs otherwise.

Therefore, ABC or XYZ will have to abide by the abovementioned conditions.

Under the TM Act, a registered trademark can be assigned or transmitted with or without goodwill of the business concerned. An assignment of a trademark must be in writing. No specific form has been prescribed. There are certain restrictions when assigning a trademark. Assignment should not result in the creation of concurrent exclusive rights in more than one person to the use of the same mark or similar mark in respect of the same or similar goods, if such use in exercise of those rights would be likely to deceive or cause confusion. Confusion or deception can be avoided by territorial limitation or limitation of the goods. Registration of assignment is necessary to establish title to the registered mark.

Under the Copyright Act, it is seldom that an author of a copyright himself exploits the work for monetary benefit. Ordinarily, he either assigns the whole or part of his rights to others to exploit economically for a lumpsum consideration. Assignment of copyright is valid only if it is written and signed by the assignor or by his duly authorised agent. There is no prescribed form for assignment. The deed of assignment should contain the following:

- (a) the identity of the work;
- (b) the rights assigned and the duration and territorial extent of such assignment; and
- (c) the amount of royalty payable, if any, to the author or his legal heirs during the currency of the assignment.

Registration of the assignment is not necessary for its validity.

Therefore, ABC or XYZ will have to abide by the abovementioned conditions.

Basic Contractual Issues

Preliminary Secrecy Agreement

It would be advisable for ABC to enter into a confidentiality and non-disclosure agreement, prior to commencing negotiations as well as post-termination (normally incorporated in the agreement), in order to protect the information from being divulged to others.

The following are standard clauses of a secrecy agreement:

“Definitions

Confidential Information shall mean ABC’s proprietary and confidential information relating to the pharmaceutical industry, including, without limitation, information, data, statistics, drawings, graphs, records, physical samples, summaries, extracts, etc. of any nature whatsoever on soil conditions, building materials, prices, either in written, electronic, machine readable or any other form;”

“Obligations of the Parties

1. XYZ shall hold in confidence any and all Confidential Information, provided and furnished to it by ABC, whether directly or indirectly, and whether or not provided or furnished prior to the date hereof. However, this obligation shall not apply to any part of the Confidential Information disclosed:
 - 1.1 which prior to the time of disclosure is in the public domain; or
 - 1.2 which after disclosure by ABC becomes part of the public domain by publication or otherwise through no fault of the XYZ; or
 - 1.3 which prior to the time of disclosure by ABC is already in the possession of XYZ and was not previously acquired by it from ABC under an obligation of confidence; or
 - 1.4 which is made available to XYZ by an independent third party, provided, however, that such Confidential Information was not made available in breach of any obligation of confidence or non-use owed, directly or indirectly, by XYZ or the independent third party to ABC; or
 - 1.5 which is required by law to be disclosed, provided that prior to such disclosure sufficient notice in writing of the same is given to ABC in order that ABC may seek a protective order or other appropriate remedy; or
 - 1.6 which is disclosed orally, unless identified as Confidential Information at the time of disclosure and confirmed as such in writing by ABC at the time of disclosure.

In each case, the Party invoking any of the foregoing exceptions shall bear the burden of proof.

2. XYZ undertakes to maintain the Confidential Information received in strict confidence, but without prejudice to the generality of the foregoing, (i) not to make any commercial use thereof, and (ii) not to use the same for the benefit of itself or for any third party except as otherwise agreed in writing between the Parties hereto.

3. XYZ undertakes to apply such security measures and degree of care as will be required to keep all Confidential Information strictly confidential and to protect such Confidential Information from any unauthorised disclosure, copying or use.
4. XYZ agrees to limit disclosure of the Confidential Information received to only those of its directors, officers, employees, agents, family members, professional advisors, who need to know the same and then only after such directors, officers, employees, agents, family members, professional advisors have undertaken to comply with obligations corresponding to those undertaken by XYZ under this Agreement, to the satisfaction of ABC. XYZ irrevocably agrees and accepts full responsibility and liability for its directors, officers, employees, agents, family members, professional advisors and becoming privy to the Confidential Information to maintain confidentiality in respect of the Confidential Information and expressly not to circumvent in any manner whatsoever the provisions of this Agreement.
5. At the written request of ABC, XYZ agrees to promptly return all Confidential Information received from ABC pursuant to this Agreement. XYZ shall not retain any originals or copies of ABC's Confidential Information and shall certify to that effect.
6. XYZ represents that it has no obligations or commitments inconsistent with this Agreement.
7. The discussions being held pursuant to the execution hereof are confidential and are to be treated as Confidential Information according to the terms of this Agreement.”

Layout of the R&D Contract

The R&D contract should be structured in a manner that best reflects the intentions of both the parties. Although it varies from agreement to agreement, some of the main issues which should be reflected in a R&D contract are:

- (a) Term of the Contract;
- (b) Obligations of the respective parties;

- (c) Ownership of Innovations;
- (d) Ownership of existing Intellectual Property;
- (e) Confidentiality and Non-Compete;
- (f) Representations and Warranties; and
- (g) Indemnification clause.

Object of the R&D Contract

The object of the R&D contract is to encourage scientific research, new technology and industrial process development between the respective parties.

Definition of IP rights

See clause 3 (*infra.*)

Main Contractual Issues

Background Rights

In order to protect sensitive information from being divulged to others, confidentiality and non-disclosure agreements should be entered into by ABC and XYZ, prior to commencing negotiations as well as post-termination (normally incorporated in the agreement).

As ABC is bringing in the technology, it would be advisable for ABC to negotiate with XYZ by inserting a clause whereby ABC is permitted to deal with its IP rights for purposes other than the existing R&D Contract as well.

Indian courts enforce these agreements and grant injunctions on adequate proof of breach or proposed breach being adduced. However, due to systemic delays, suits for damages take a fairly long time to reach hearing. Therefore, although an injunction may be granted urgently, a decree awarding damages to the injured party may take some time.

Breach of confidentiality agreements do not give rise to any criminal liabilities in India, unless the aggrieved party can prove the *mens rea* aspect of criminal breach of trust in usurpation of specific incorporeal property, and/or cheating, which are offences under the Indian Penal Code, 1860.

Definition of Background Rights

For the purpose of R&D Contracts a standard clause is as follows:

“Ownership of Intellectual Property

1. ABC and XYZ agree that any intellectual property, that is, process patents, copyrights, etc.) owned by ABC or XYZ prior to signing of the Agreement shall remain the property of ABC or XYZ as appropriate.
2. The intellectual property, that is knowhow processes, designs, techniques, patents, copyrights, etc., generated in the R&D Contract, shall be owned in its entirety by both ABC and XYZ with neither ABC nor XYZ having any more or less rights to the intellectual property as the other party except as described in this Agreement”.

Foreground Rights

Please incorporate the discussion in Clause 3 above by reference. Note that where a patent is granted to two or more persons, each of the co-owners, in the absence of any agreement to the contrary, is entitled to an equal undivided share in the patent. Therefore, ABC and XYZ is entitled, by himself to make, use or exercise the patent without accounting to the others. In such a case, ABC and/or XYZ cannot assign or licence the patent except with the consent of the other (section 50(2) of the Patents Act) This is, however, subject to any agreement to the contrary. If consent is not given, ABC or XYZ, as applicable, may apply to the Controller of Patents in the prescribed manner for issue of directions as to the sale, lease of the patent, or any interest therein.

Definition of Foreground Rights

A standard clause for the purpose of R&D Contracts is listed in Clause 4.

Acceptance of Results

Under Indian law, acceptance of the result developed pursuant to a R&D Contract is necessary before the process developed can be granted a legal status. Assuming that ABC and XYZ have created an invention, they should patent the same.

As mentioned above not all inventions are capable of being patented. ABC or XYZ upon inventing the process must file an application for a patent accompanied by either a provisional specification or a complete specification. Thereafter, the application is examined by the Patents Office. Once the Controller is satisfied with the specification, he will accept the specification and advertise the same. Any person interested in giving notice of opposition to the Controller at the appropriate office of the Patent Office, to the grant of the patent may do so in the prescribed form. In case there is no opposition, the proceeding is finally decided in favour of the applicant for grant of patent.

Listed herein below is a standard clause dealing with the acceptance of the R&D work:

- “1. ABC and XYZ agree to cooperate in providing adequate information to each other so as to facilitate and complete the procedural and other requirements for obtaining protection of the Intellectual Property from infringement through but not limited to patents and copyrights ("Intellectual Property Rights" or "IPRs") if ABC and XYZ jointly decide that such rights should be obtained in India and/or abroad. In that case, XYZ shall file, maintain, defend and bear expenditure for IPRs (including patents) in India, and ABC shall file, maintain, defend and bear expenditure for IPRs outside India.

2. ABC and XYZ agree that either party cannot abandon any application for any IPR pertaining to the R&D Contract, without the written consent of the other party, except that either party may abandon any such application without the written consent of the other party if the abandoning party permits the other party to take over the application and transfers all ownership of IPR arising from such application to the other party without any compensation of any kind.”

Exploitation of Results

Generally, parties do provide for in a R&D Contract, the manner in which the result developed by ABC and XYZ is to be exploited in different ways. In the present case, ABC may decide to exploit the patent granted, assign its rights, or licence them to

another party for a lumpsum payment or on a royalty basis. The purpose of applying for a patent is to seek an exclusive right to use the invention, the right to manufacture the invented product and market it.

“Utilization of Intellectual Property Developed

1. During the period between the execution of the Agreement and ending 60 months after completion of the R&D Contract, ABC shall have the exclusive option (the "Option") to enter into an agreement(s) with XYZ to commercially exploit/use any or all of the Intellectual Property [the "Commercial Use Agreement(s)"]. The Commercial Use Agreement(s) shall be negotiated in good faith and mutually agreed to in writing by ABC and XYZ, and shall include a timetable for commercializing any such Intellectual Property, but the fees and or royalties payable by XYZ to ABC shall not exceed two per cent of the turnover (net sales of any products) directly attributable to Intellectual Property.
2. Any use of the intellectual property for commercial purposes by either ABC or XYZ shall require the mutual consent of ABC and XYZ. ABC shall have the right to license the intellectual property.
3. ABC and XYZ agree that in the event of licensing the Intellectual Property to a third party, the terms and conditions of licensing and sharing of the money realized thereof shall be agreed to mutually in writing between ABC and XYZ.
4. In the event scientists should make discoveries or inventions or otherwise develop intellectual property unrelated to the objectives of the R&D Contract, during the work as envisaged under the Agreement, ABC shall retain rights to such intellectual property. ABC shall first offer such intellectual property to XYZ under separate terms and agreement. In the event XYZ does not accept the offer within six weeks of the date of the receipt of the offer in writing. ABC shall be free to negotiate the license of such intellectual property to other parties without any obligations to XYZ, provided ABC does not offer license terms to other parties more favourable than offered to XYZ.”

Transfer of IP Rights and Know-How by a Licence

The Patents Act, Copyright Act and the TM Act are applicable to the transfer of IP rights under license agreements. If ABC or XYZ propose to transfer their IP rights and Know-how by form of a licence, then they would have to abide by the conditions as mentioned hereinbelow.

Under the Patents Act, a patent is a transferable property. It can be transferred from the original patentee to any other person by assignment by the patentee or by operation of law. Transfer of a patent can also occur by grant of license by the patentee to another person to work the patented invention. A licence is not valid unless it is in writing and an application for registration of the document embodying the terms of licence is filed with the Controller of Patents. Where there is an agreement to pay royalties at a rate mentioned for all articles made under under a patent , such agreement may in effect constitute a licence. A licence to use the patent may be granted after filing the provisional specification. A licence may be express, implied or statutory. It may be exclusive, non-exclusive or limited.

It is unlawful to insert certain kinds of restrictive conditions in any contract relating to a license to use the patent. For example, to prohibit the licensee from acquiring except from the licensor any article other than the patented article or an article other than that made by the patented process is void condition. However, patentees are allowed the liberty to impose certain restraints on the licensees. For instance, a patentee may restrain the licensee from selling the patented article in a particular territory or not to seek items manufactured by patentees competitors. However, the patentee cannot impose restrictions on the licensees which are against public interest. Note however, a patentee who has licensed a wholesaler or retailer to sell the patented article may prohibit them from selling his competitor's goods.

Under the TM Act, licensing of trademarks other than by way of registered users may not be objectionable provided the licensing does not result in causing confusion or deception among the public.

Under the Copyright Act, a licence is a grant of authority to do a particular thing. It transfers an interest to a limited extent, whereby the licensee acquires an equitable right only in the copyright. Licences may be exclusive, or non-exclusive. Non-exclusive licence is not defined under the Copyright Act. The term exclusive license is defined in section 2(f) of the Copyright Act. It confers on the licensee and persons

authorized by him, to the exclusion of all other persons, including the owner of the copyright, any right comprised in the copyright in a work.

Exclusivity/Restriction on Competition or Stipulating Non-competition Obligations

Depending upon the degree, extent of rights conferred on the licensee, a license may be exclusive or non-exclusive license. An exclusive license confers all exclusive rights, to make, distribute or sell, on the licensee excluding all other persons. By the Patents (Amendment) Act, 1999, a new provision has been inserted which deals with exclusive marketing rights to sell or distribute an article or substance in India. An application must be made to the Controller of Patents. If the Controller is satisfied with the application then he proceeds to grant exclusive right to sell or distribute.

Another example of a restrictive covenant commonly incorporated in an agreement is a covenant not to compete. ABC or XYZ may insert a clause whereby either of the parties are prevented from undertaking a business similar to theirs during the term of the contract and for a certain number of years after termination. Duration of post-termination restrictions depend on the nature of the business. Indemnities for protection against breach of such covenants are also taken. However, in a recent development, the Director General of Investigation and Registration has filed an application under the MRTP Act against an Indian company and its foreign joint venture partner on the grounds that a non-compete clause in an agreement amounts to a per se restrictive trade practice. (*Source: The Economic Times, Mumbai, 27 September 1999*) The application is pending and one does not know the fate thereof.

“Covenant not to Compete

1. During the term of this Agreement, no Party (including any of their Affiliates) shall engage in or knowingly cause a third Party to engage in, the manufacture or R&D of the Products in India.
2. During the term of this Agreement, no Party shall solicit or assist any other Person to solicit any business from any present or past customer of the other Party; or request or advise any present or future customer of the other Party or any of its Affiliates, to withdraw, curtail or cancel its business dealings with the other Party or any of its Affiliates; or commit any other act or assist others to commit any other act which might injure the business of the other Party or any of its Affiliates.

3. During the term of this Agreement, no Party shall directly or indirectly (i) solicit or encourage any employee of the other Party or any of its Affiliates to leave the employ of any such entity or (ii) hire any employee who has left the employment of the other Party or any of its Affiliates if such hiring is to occur within one year after the termination of such employee's employment with the other Party or any such Affiliate.
4. During the term of this Agreement, no Party shall directly or indirectly solicit or encourage any consultant then under contract with the other Party or any of its Affiliates to cease work with such entity.”

Additional clauses for assignment of IP rights are as follows:

1. All right, title and interest in the data, information, documents and results arising out of the Trial and in the know-how incidental thereto and any patent applications and patents resulting from any inventions or discoveries made during the performance of the Services by XYZ India hereunder shall be owned and be the exclusive property of ABC India and may be used and/or transferred by ABC India in its sole discretion without any further payment to XYZ India. ABC India may use this information in any way it deems fit, including, but not limited to, regulatory filings, publication, disclosure to Affiliates and third Parties. Notwithstanding the foregoing, ABC India acknowledges that XYZ India possesses certain inventions, processes, know-how, trade secrets, intellectual properties and other assets, including, but not limited to, analytical methods, computer technical expertise and software which have been independently developed by XYZ India (collectively “XYZ’S Property”). ABC India and XYZ India agree that any of XYZ’S Property or improvements thereto which are used, improved, modified or developed by XYZ India under or during the term of this Agreement are the product of XYZ India’s technical expertise, possessed and developed by XYZ India prior to or during the performance of this Agreement and are the sole and exclusive property of XYZ India.
2. If ABC India or its Affiliates decide to file patent applications covering any innovations, inventions, etc. resulting from the performance of the Services or the Trial, XYZ India shall, at ABC India’s request and expense, assist ABC India or its Affiliates in the preparation and prosecution of such patent applications and shall execute such documents as may be deemed necessary by ABC India or its Affiliates for the filing thereof or for the vesting in ABC

India or its Affiliates of the title thereto. XYZ India irrevocably appoints severally ABC India and each of the directors and secretaries for the time being of ABC India to be its attorneys in its name and on its behalf to execute all such instruments and do all such things and generally to use XYZ India's name for the purpose of assuring to ABC India (or its Affiliates) the full benefit of the provisions of this Article and agrees that any instrument in favour of a third Party in writing signed by any director or secretary for the time being of ABC India falling within the authority hereby conferred shall be conclusive evidence in that regard.

Warranty/Liability

Areas of Warranties

Normally, parties provide for the following general representations and warranties when entering into a R&D Contract. Specific warranties may also be included regarding the subject of R&D. But they are negotiated.

“Representations and Warranties

1. Each Party warrants and represents to the other that:
 - (i) it is properly established under the laws of XYZ and has complied with all requirements in connection with its formation;
 - (ii) it has the power to undertake, exercise its rights and perform and comply with its obligations under this Agreement;
 - (iii) all actions, conditions and things required to be taken, fulfilled and done in order:
 - (A) to enable it lawfully to undertake, exercise its rights and perform its obligations under this Agreement; and
 - (B) to ensure that its obligations under this Agreement are valid, legally binding and enforceable,

have been taken, fulfilled and done;

(iv) its entry into, exercise of its rights and/or performance of or compliance with its obligations under this Agreement does not and will not violate or exceed any restriction imposed by:

- (A) the laws to which it is subject; or
- (B) its constitution; or
- (C) an agreement to which it is a Party or which is binding on its assets,

and

(v) its obligations under this Agreement are valid, binding and enforceable.

Culpa in Contrahendo

It is rare that parties do not provide for specific warranties when entering into R&D Contracts and fail to insert provisions pertaining to access to Background Rights and use of the results of R&D Contract. However, in cases where parties fail to so provide, the Indian Contract Act and the IP laws specified above will govern the rights of the parties.

Remedies

Breach of an agreed contractual term in conformity to Indian IP laws can entitle the aggrieved party to specific performance of the term, or injunction and damages for breach of contract.

Employment Matters

Right to inventions

Under the Copyright Act, employees as such are not granted statutory rights to inventions made in the service of an employer. Under the Copyright Act, section 17 statutorily recognises the author of the work to be the first owner of the copyright therein. Where a work is made in the course of the author's employment under a contract of service or apprenticeship, the employer (not being the proprietor of a newspaper, magazine or periodical), in absence of a contract to the contrary, the employer will be the first owner of the copyright in the work so created. There are however, some exceptions to this rule.

If however, a person employs another to do a certain work but leaves it to the other to decide how that work shall be done, what steps shall be taken to produce that desired effect, then it is a contract for service. His status is that of an independent contractor, as he decides about the manner of doing work. In such cases the copyright vests in him and not the employer.

However, under section 57 of the Copyright Act, should an employee's research work (assigned to the employer) be altered in such a way so as to reflect adversely upon the employee, the employee can assert his moral rights.

ABC and XYZ should therefore be aware of such situations and enter into assignment agreements with the employees to protect their interests.

Competition Law

The national competition authorities are allowed to interfere with R&D Contracts in certain circumstances, more particularly mentioned hereinbelow.

In India, the Monopolistic & Restrictive Trade Practices Act, 1969 (the "MRTP Act") was enacted to ensure that the operation of the economic system did not result in the concentration of economic power. The basic philosophy behind the MRTP Act was not to inhibit industrial growth in any manner but to ensure that such growth was channeled for the public good. The Monopolistic Restrictive & Unfair Trade Practices Commission had jurisdiction in respect of claims relating to abuse of economic power. However, in 1991, the provisions relating to concentration of economic power were dropped from the MRTP Act, and the MRTP Act now focuses mainly on restrictive and unfair trade practices.

Every agreement which incorporates highly restrictive terms would bring it within the purview of the MRTP Act and lay it open to scrutiny by the Director General of Investigation & Registration or the MRTP Commission.

Restrictive trade practice, as defined, means "a trade practice which has or may have the effect of preventing, distorting or restricting competition" {Section 2(o)}. Thus, the first inquiry under the MRTP Act is into the restrictive nature of the trade practice as it relates to the effect on competition. Also, since the main purpose of the MRTP Act is to protect the public, an inquiry into the effect on public interest is always made.

Various categories of agreements enumerated under section 33(1), including agreements which restrict persons from whom certain goods can be purchased, have been recognized to be *per se* restrictive. The consequence of falling within one of these enumerated clauses is that agreements between parties relating to such *per se* restrictive trade practices must be registered with the Director General (pursuant to section 35). However, such agreements are not *per se* void or illegal. The Commission still needs to make an inquiry (pursuant to section 37) as to whether the agreements are prejudicial to public interest. Until the time the Commission declares the agreements as prejudicial to public interest, the parties may continue to conduct trade and business under such agreements.

The decision to register or not register an agreement lies with the parties to the agreement. However, if an inquiry is made by the Commission who feels that an agreement should have been registered but was not, the burden of proof lies with the parties to prove that the agreement does not fall within one of the enumerated clauses of section 33(1).

Again, simply by registering an agreement with the Director General does not result in conceding that the agreement is one relating to restrictive trade practices. Rather, the Commission is still required to inquire (pursuant to section 37) if the agreement is prejudicial to public interest. After an inquiry, if the Commission finds that the agreement is prejudicial to the public's interest, only then does the agreement become void.

If a company as party to an agreement, is liable for registration under section 35 read with section 33(1), does not register, each member of that company is penalised for the default {pursuant to section 48(1)}.

Conclusion

The new patent regime in India will stimulate research and development in India. Companies like ABC, who were earlier hesitant to do R&D in India, will invest money into the pharmaceutical sector and bring in international best practices.