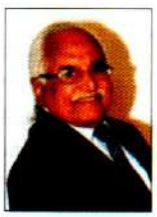
Technology Transfer during Outsourcing

With outsourcing and contract manufacturing well-established in the commercialization strategies of most pharmaceutical and biopharmaceutical companies, technology transfer becomes an enabling asset. Outsourcing and technology transfer provide firms with the platform for developing capability to achieve superior performance in the marketplace.



Dr Gopakumar G Nair
CEO
Gopakumar Nair Associates

The concept of CRAMS (Contract Research and Manufacturing Services) has its origin in India, as claimed by Hyderabad based leading CRAMS corporate. CRAMS is essentially rooted in outsourcing of research and/ or manufacturing. Technology is the key element bonding the parties together in any outsourcing venture. Various agencies are projecting high CAGR (compounded Average Growth Rate). CARE expects 18 to 20 per cent growth rate by 2018, while Cygrus Research reports that global pharmaceutical outsourcing worth US$58 billion in 2009 and US$85 billion in 2012 is expected to grow at a CCGR of 47.2 per cent earlier to 62.51 per cent in recent times, being the Indian pharma's CRAM growth rate.

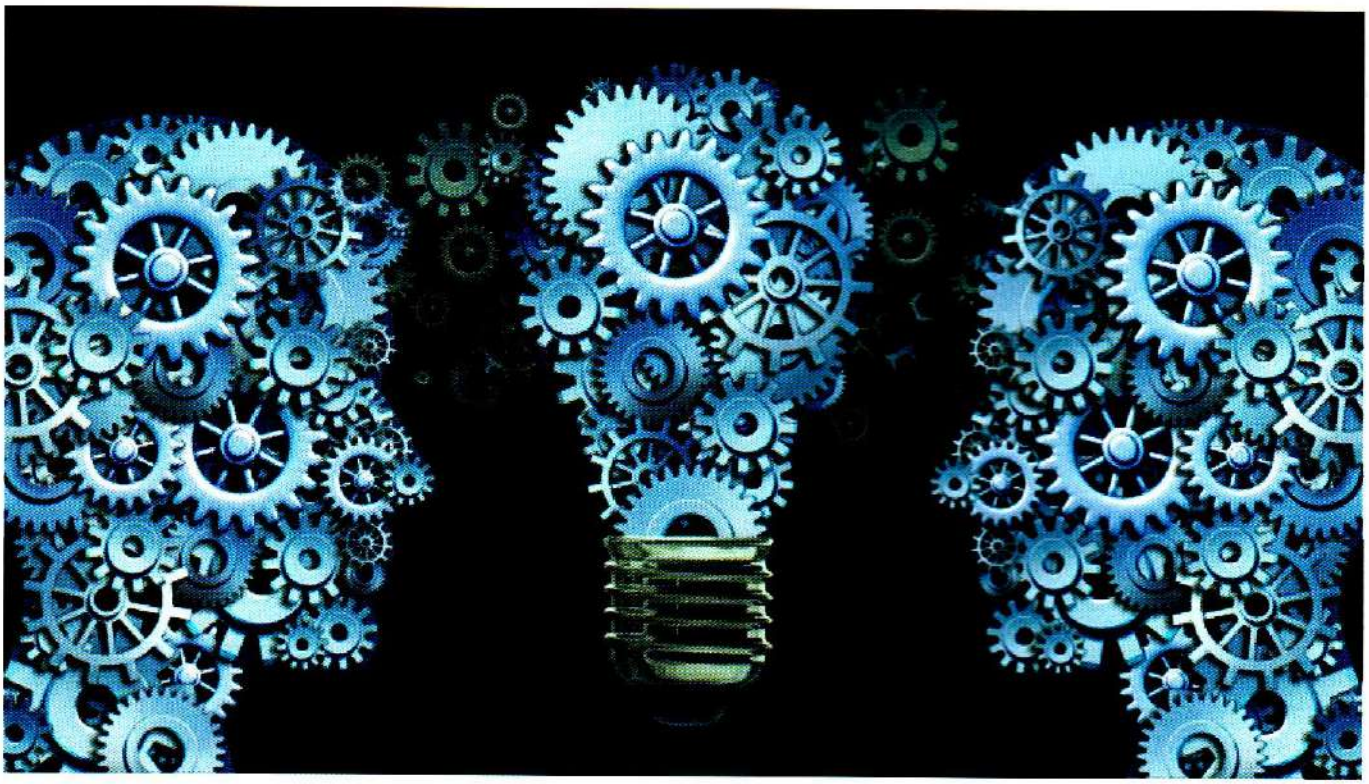
Technavio forecasts Indian CRAM market to grow at CAGR of 32.67 per cent during 2013 to 2018. Current active players include Biocon, Dishman Pharmaceuticals and Chemicals, Divis Laboratories, Jubilant Life Sciences, Piramal Healthcare amongst others. There are CROs such as Quintiles, Covance, Parexel, SIRO Clinpharm vying for a piece of the CRAM pie.

In recent times, Rusan Pharma has emerged as a strong CRAM principal manufacturer and technology provided especially for skin patches and technologically advanced inserts and patches. According to UBM, CRAMs is expected to touch USD 19 billion by 2018.

CRAMs have the key parties, who are the principals who own the facilities / infrastructure and the outsourcers who seek the use of the Principal's facilities for conducting research and / or manufacturing. The CRAM relationship commences with an MOU followed by or directly with a contractual Agreement specifying the terms and conditions thereof. The most important element of such agreements is the confidentiality for non-disclosure/non-compete clauses relating to the technologies disclosed by one party to the other. Technology may get disclosed to the outsourcer from the Principal, CRAM organization, if the product or process involves high technology. On the other hand, if the Outsourcer is possessing the high technology in the product or the process, and the manufacturer is having convectional facility, the non-disclosure and non-compete component of the Contract Agreement becomes very critical for the outsourcer.

Further, once the technology having Intellectual Property (IP) content is disclosed and put to work and practice, new IPs either in the form of incremental infringements meriting new product or process patent applications or any disruptive innovations mined during the operations arising from the CRAM arrangement need to be designed for IP sharing conditions and provisions in the Contract/Agreement. This is the most critical area to be taken cautions drafting in the contract. Very often, when CRAM contracts are signed, the aspects of IP sharing and more importantly, the roadmap for the sharing of the new IP being generated through the operation of the CRAM relationship, does not get the attention it deserves. A few templates, historical disputes and litigations with few examples of technology transfer in outsourcing are discussed hereafter.

Technology transfer in outsourcing is substantially related to intangibles such as Intellectual Properties, know-how, confidential technical information and diagrams of flowchart and hardware. The Technical Knowledge as transferred is the key element, which includes formulas, flowcharts, diagrams, drawings, blueprints and operating manuals. Subsequent



improvements on the shop floor of the transferee or outsourced principal party need to be specifically covered with regard to the IP sharing terms. The equipments, reactors, machinery including related software also forms part of the technology transfer. Provisions need to be built in for improvements likely to be made at the outsourcing site in future during operations.

Firewalls for protecting or limiting the dissemination of know-how only to the key persons need to form part of the technology transfer agreements. Non-disclosure to unrelated parties and non-compete clauses need to be incorporated. Restrictive clauses on territorial jurisdictions and end-use limitations as well as licensing exclusivities also need to be part of the agreement. Agreement need to specify if it is exclusive, non-exclusive or for fixed areas or fields or period of time. Warranties and indemnities also form important clauses to be carefully worded and drafted. Technology transfer fee, royalty, if any, terms of payment such as one time out right lumpsum payment or/and payments across milestones etc. need to be negotiated, crystallised and incorporated in the agreement without ambiguity. An aspect which is often overlooked is the termination clauses and applicable laws. Option of arbitration or court litigation for settlement of disputes is another area of importance to be incorporated in agreement.

WIPO has conducted a multi-country Survey on Technology Transfer Agreements (TTA). The results of the survey are available on http://www.wipo.int/export/sites/www/ip-competition/en/studies/tta_survey.pdf. Srijit Mukherjee and Sudipta Bhattacharjee in their well-articulated article in Journal of Intellectual Property Rights, Vol. 9, May 2004 P-260-274, has dealt with "Technology Transfer and the Intellectual Property issues emerging from it - An Analysis from a Development Country Perspective."

The Patents Act, 1970 (of India) as well as most Patent Acts of the countries have provisions on Patent Assignments and licensing to third parties. Patents being critical components of Technology Transfer, the terms of Patent Assignments or licensing, assures importance in Technology Transfer Agreements (TTAs). Section 68, Section 69 and Rules 90 to 92, cover essential aspects of Patent Assignments and transfer of titles in patent register. An important provision under Patents Act, 1970 to be taken cautionary note of, is Section 140 - "Avoidance of Certain Restrictive Conditions". Very often Technology Transfers involving Patented technologies overlook the provisions in Section 140 while drafting restrictive clauses beyond legal boundaries permissible.

While all precautions and eventualities need to be taken into account while drafting Technology Transfer Agreements, care and caution is recommended to ensure that the terms and conditions are not unduly restrictive beyond legally enforceable limits and contours.

Contact: gopanair@gnaipr.net